STATE OF CALIFORNIA ARNOLD SCHWARZENEGGER, Governor

Board of Chiropractic Examiners
2525 Natomas Park Drive, Suite 260
Sacramento, California 95833-2931
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CA Relay Service TT/TDD (800) 735-2929
Consumer Complaint Hotline (866) 543-1311
http://www.chiro.ca.gov

NOTICE OF PUBLIC MEETING

March 26, 2009
9:30 a.m.
Burbank Airport Marriott and Convention Center
2500 Hollywood Way
Burbank, CA 91505
(818) 843-6000

AGENDA

1. **PUBLIC SESSION Call to Order**

   Frederick Lerner, D.C., Chair
   Hugh Lubkin, D.C., Vice-Chair
   Francesco Columbu, D.C., Secretary
   Martin Mariscal, Public Member
   Jeffrey Steinhardt, D.C.
   Richard Tyler, D.C.

2. **CLOSED SESSION:**
   Pursuant to California Government Code Section 11126(e)
   A. Catherine Hayes v. Board of Chiropractic Examiners
      Sacramento County Superior Court Case No. 34-2008-00006473
   B. David Hinchee v. Board of Chiropractic Examiners, Cathy Hayes
      Sacramento County Superior Court, Case No. 07AS03721
   C. Board of Chiropractic Examiners v. Carole M. Arbuckle
      Sacramento County Superior Court, Case No, 03AS00948

3. **PUBLIC SESSION:** Announcements Regarding Closed Session

4. **Swearing In of New Board Members**
   A. Martin Mariscal, Public Member
   B. Jeffery Steinhardt, D.C.

5. **Chair's Report**

6. **Committee Member Assignments**

7. **Approval of Minutes**
   January 8, 2009 Board Meeting

8. **Public Comment**

9. **Ethical Decision Making and Other Legal Training**

10. **Executive Officer's Report**
    A. Budget
    B. Personnel

C. Licensing
D. Enforcement
E. Web Casting Update
F. Final Report to the Bureau of State Audits
G. Status of Chiropractic Consultant Position

11. Approval of Out of State Travel Blanket

12. Ratification of Approved Continuing Education Providers

13. Ratification of Approved License Applications

14. Ratification of Denied License Applications in Which the Applicants Did Not Request a Hearing

15. Recommendation to Waive Two Year Requirement to Restore a Cancelled License

16. Legislative Committee Report
A. Proposed Fee Increase
B. AB 361 (Lowenthal)
C. SB 389 (Negrette-McCleod)
D. SB 762 (Aanestad)
E. Any other legislative bills of interest to the Board

17. Proposed Regulations
A. Letter of Admonishment
B. Chiropractic Quality Review Panels
C. Manipulation Under Anesthesia
D. Continuing Education
E. Time Frame to Petition for Reinstatement of a License and Modification of Probation or Early Termination of Probation
F. Recognition of Chiropractic Specialties

18. Public Comment

19. Future Agenda Items

20. Hearings re: Petition for Reinstatement of Revoked License:
A. Barney Nenadov
B. Barry Michaels
C. Richard Greenland

21. CLOSED SESSION:
Deliberation on Disciplinary Matters and Possible Action on Disciplinary Decisions Pursuant to California Government Code Section 11126(c)(3)

22. PUBLIC SESSION: Announcements Regarding Closed Session

23. Adjournment

The Board of Chiropractic Examiners' paramount responsibility is to protect California consumers from the fraudulent, negligent, or incompetent practice of chiropractic care.

Meetings of the Board of Chiropractic Examiners are open to the public except when specifically noticed otherwise in accordance with the Public Meetings Act. Public comments will be taken on agenda items at the time the specific item is raised. The Board may take action on any item listed on the agenda, unless listed as informational only. All times are approximate and subject to change. Agenda items may be taken out of order to accommodate speakers and to maintain a quorum. The meeting may be cancelled without notice. For verification of the meeting, call (916) 263-5355 or access the Board's Web Site at **www.chiro.ca.gov.**

The meeting is accessible to persons with physical disabilities. If a person needs disability-related accommodations or modifications in order to participate in the meeting, please make a request no later than five working days before the meeting to the Board by contacting Marlene Valencia at (916) 263-5355 ext. 5363 or sending a written request to that person at the Board of Chiropractic Examiners, 2525 Natomas Park Drive, Suite 260, Sacramento, CA 95833. Requests for further information should be directed to Ms. Valencia at the same address and telephone number.

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Governor Schwarzenegger Announces an Appointment to the State Board of Chiropractic Examiners

Martin Mariscal, 51, of Santa Maria, has been appointed to the State Board of Chiropractic Examiners. Since 2000, he has served as president and chief executive officer of Mariscal-Rumbaugh Insurance Agency. Prior to that, he owned Martin Mariscal Insurance from 1986 to 1999 and was an insurance agent for Acquistapace Insurance Service from 1983 to 1986. From 1980 to 1983, he was a marketing representative for Certified Pension Consultants. He is a member of the Board of Vocational Nursing and Psychiatric Technicians, National Association of Insurance and Financial Advisors, Western Insurance Agents Association, Insurance Brokers Association, IBA West and Rotary International. This appointment does not require Senate confirmation and the compensation is $100 per diem. Mariscal is a Republican.

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Governor Schwarzenegger Announces an Appointment to the State Board of Chiropractic Examiners

Jeffrey Steinhardt, 53, of La Jolla, has been appointed to the State Board of Chiropractic Examiners. He has served as a chiropractor in private practice since 1984. Steinhardt is a member of the California Chiropractic Association, California Society of Industrial Medicine and Surgery, San Diego Chiropractic Network, American Public Health Association and Academy of Forensic and Industrial Chiropractic Consultants. This position does not require Senate confirmation and the compensation is $100 per diem. Steinhardt is a Republican.

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Committee Assignments
Revised March 2009

Committee	Members	Responsibilities
Continuing Education	Hugh Lubkin, D.C. (Chair) Richard Tyler, D.C.	Proposes polices, standards and approves CE providers
Enforcement	Hugh Lubkin, D.C. (Chair) Jeffrey Steinhardt, D.C.	Proposes regulations, policies, and standards to ensure compliance with chiropractic law and regulations
Government Relations	Hugh Lubkin, D.C. (Chair) Martin Mariscal	Proposes polices to address audit and Sunset Review Committee deficiencies; oversees all administrative issues regarding BCE operations
Legislation / Regulation	Frederick Lerner, D.C. (Chair) Francesco Columbu, D.C.	Proposes positions on legislative bills and regulatory matters
Licensing	Jeffrey Steinhardt, D.C. (Chair) Richard Tyler, D.C.	Proposes policies and standards regarding chiropractic colleges doctors of chiropractic and satellite offices
Public Relations	Martin Mariscal, (Chair) Fred Lerner, D.C.	Develops strategies to communicate with the public through various forms of media.
Scope of Practice	Hugh Lubkin, D.C., (Chair) Fred Lerner, D.C.	Reviews and proposes positions on scope of practice issues
Strategic Planning	Francesco Columbu, D.C. (Chair) Martin Mariscal	Develops draft Strategic Plans and monitors the BCE's progress in achieving goals and objectives

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BOARD OF CHIROPRACTIC EXAMINERS
PUBLIC SESSION MINUTES
January 8, 2009
State Capitol
Senate Room 112
Sacramento, CA 95814

Board Members Present

Frederick Lerner, D.C., Chair
Hugh Lubkin, D.C., Vice Chair
Francesco Columbu, D.C., Secretary
Jim Conran, Public Member
Judge James Duvaras, Public Member
Richard Tyler, D. C., Professional Member

Staff Present

Brian Stiger, Executive Officer
LaVonne Powell, Senior Staff Council
April Alameda, Associate Governmental Program Analyst
Lavella Matthews, Associate Governmental Program Analyst
Rebecca Rust, Associate Governmental Program Analyst
Tammi Pitto, Staff Services Analyst
Valerie James, Office Technician

Call to Order

Dr. Lerner called the meeting to order at 9:30 a.m.

Roll Call

Dr. Columbu called the roll. All members were present.

Chair's Report

Dr. Lerner wished everyone a happy and healthy New Year and made the following comments: Looking back at 2008, it was very productive and successful. The Board began developing regulations to further protect the public. Today we are presenting six regulations, some of which are simple, others of which months have been spent developing along with public members, professional associations, chiropractic schools and colleges, board staff and legal council.

Through the efforts of our Executive Officer, Brian Stiger, we developed a full board staff to handle the day to day activities and requirements of the board. The staff has accomplished an amazing body of work in a very short time. They should all be commended for their efforts. On behalf of the board members, I would like to express my deep gratitude for all that is being accomplished. We continue to benefit from the wisdom and experience of our legal council Ms. LaVonne Powell and Mr. Tom Rinaldi, Deputy Attorney General. As chair of BCE for 2008, it's been a great pleasure and honor to serve with my fellow board members. In my experience, they have moved forward with great professionalism and accomplished more in this past year, than in many previous years put together. Anyone can look at today's agenda to see how far we have progressed in such a sort time. As my 2008 term draws to a close today, presiding over the board has been one of the most satisfying experiences of my life. I thank my fellow board members for the strengths you all bring to the board. As one could see from the agenda today, 2009 is starting at full speed.

Election of Officers for 2009

A. Chair

MOTION: MR. CONRAN NOMINATED DR. LERNER AS CHAIR OF THE BOARD
SECOND: DR. LUBKIN SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED

B. Vice Chair

MOTION: MR. CONRAN NOMINATED DR. LUBKIN AS VICE CHAIR OF THE BOARD
SECOND: JUSDGE DUVARES SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED

C. Secretary

MOTION: MR. CONRAN NOMINATED DR. COLUMBU AS SECRETARY OF THE BOARD
SECOND: DR. TYLER SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED

Approval of Minutes

November 20, 2008.

MOTION: DR. LERNER MOVED TO APPROVE THE NOVEMBER 20, 2008 MINUTES AS AMENDED
SECOND: DR. COLUMBU SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED

Discussion

Mr. Stiger stated on the last page, Dr. Tyler found a correction. The minutes need to be corrected to show that only one of the petitioners was heard.

Public Comment

Charles Davis, D.C. wanted to congratulate the Board on all their work this past year, including the staff and legal council. So much was accomplished this last year, and he hopes to keep it going through this year.

Debbie Snow has been monitoring and writing about the board for some time now. She brought up the subject of raising the continuing education hours required. She suggested that some hours be mandated in sexual boundaries, ethics, and fraud because these are such prevalent problems across all health boards. She also suggested changing the first year practice requirement to 4-6 hours from the current requirement of none. She also gave suggestions on where to go to obtain some continuing education. The Federation of State Medical Boards and an organization called Professional Boundaries Incorporated. She offered to provide more information to Mr. Stiger.

Bill Howe, California Chiropractic Association, congratulated the officers on their re-elections. He also congratulated the board members and staff on working hard to carry out the duties to promote and protect the public's health and safety. We have come a long way and he is very appreciative that the board has open ears for input from the professional association representing doctors of chiropractic. He feels they have the same interest at heart as this regulatory board.

Board Member Training on the Bagley-Keene Open Meetings Act and other relevant laws

Dr. Lerner stated this has been left as a standing agenda item and asked if there are any questions at this time.

Ms. Powell stated there is anticipation of this coming up and happening again, the board members have done a great job in the past, but it's hard when an enforcement case hits the news paper. Many times we don't know about it and it starts with an arrest. Ms. Powell reminded everyone not to read any news articles related to enforcement actions. Mr. Stiger will keep the board members informed of what they are permitted to know.

Executive Officer's Report

Budget

Mr. Stiger informed the Board of the Governor's executive order on December 19, 2008 to furlough employees starting in February 2009. Mr. Stiger provided exhibit 7A which is more specific to our own budget, although we are projected to go into a deficit this year, he will make spending adjustments to ensure it doesn't happen.

Judge Duvaras asked if there was an increase in the cost of operation and if the costs include that of the headquarters.

Mr. Stiger responded that yes, the positions of special investigators is an increase and the lease for headquarters is included.

Personnel

Mr. Stiger informed the Board we are still recruiting for a Special Investigator in Southern California. This has been going on for several months now and we are going to have two more positions added to the Board in July. We have also been involved in an extensive amount of training over the past several months.

Licensing

Mr. Stiger discussed a project assigned by Dr. Lubkin to identify those individuals that have more than five satellite offices. This assignment has been completed, 57 licensees have been identified. The average number is 10 satellite offices.

Judge Duvaras asked if the cost of a satellite office is the same as a regular chiropractic license.

Mr. Stiger clarified that the cost of a satellite office is currently $5 a year.

Dr. Lubkin asked if the maximum number of 25 satellite office is due to computer restraints or if that is the most one particular licensee has.

Mr. Stiger responded, no according to our records, 25 satellite offices is the most any one licensee has.

Enforcement

Mr. Stiger commented that one of the areas we are most proud of is the pending complaints. There are 654 pending complaints, in previous years it has been as high as 834. We have issued 13 citations for a total of $5,150.

Mr. Lerner commended the staff for an outstanding job under difficult circumstances.

Dr. Columbu looked at several other boards and feels we are ahead of many other boards.

Web Casting Update

Mr. Stiger stated that in November this Board voted to move forward with webcasting as soon as possible. We have interviewed a few different vendors. We are moving forward with the process for purchasing the hardware. Our goal is to have the May meeting webcasted.

Dr. Lerner stated when we first looked at webcasting, it was also the ability to have audio-visual recording of the meeting that people could access by speaker or topic, who said what and when. We have had on-going difficulties with the current system of audio tapes and transcribing. He really wants to ensure we reserve all of the features.

Mr. Stiger stated we are making every effort to keep all of the features, however there are some challenges.

Ratification of Approved Continuing Education Providers

Discussion

Mr. Stiger stated this is a standing agenda item and there are no new providers since the last meeting.

Ratification of Approved License Applications

MOTION: DR. LUBKIN MOVED TO RATIFY THE APPROVED LICENSE APPLICATIONS
SECOND: DR. TYLER SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED
The Board ratified the attached list of approved license applications incorporated herein (Attachment A).

Discussion

None

Ratification of Denied License Applications in Which the Applicants Did Not Request a Hearing

Mr. Stiger explained that this is new. When we deny an application and the applicant appeals, a hearing is conducted before an administrative law judge and then a proposed decision comes to the Board for a final decision. If the applicant does not appeal, then the board never ratifies the decision. So now we are asking the board to ratify those denials of applicants that never filed for an appeal. This is an issue that came from the Bureau of State Audits.

Ms. Powell clarified that no other board does this. The only reason this board needs to do this is based on how the Initiative Act is written.

MOTION: DR. LERNER MOVED TO RATIFY THE DENIED LICENSE APPLICATIONS THAT WERE NEVER APPEALED
SECOND: JUDGE DUVARAS SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED
The Board ratified the attached list of denied license applications in which the applicants did not request a hearing incorporated herein (Attachment B).

Discussion

None

Board Newsletter

Dr. Lerner discussed that the public relations committee would like to have a newsletter. He is not aware of a newsletter in the past 7 years and feels it would be a great way for licensees and the public to stay informed.
At this time the newsletter is being proposed to run quarterly and be posted on the Board's website.

Mr. Conran feels there are many topics that could be included and that it would be a good idea to have this posted at least quarterly.
When he first joined the Board he was surprised to find out there was no newsletter being produced. He is very supportive of this idea.

Proposed Legislation to Increase License Fees

Dr. Lerner stated that the Legislative Committee met this morning and had voted to bring this to the full board for a vote. He turned this over to Mr. Stiger for presentation.

Mr. Stiger explained back in 2005, the Board expressed intentions to raise license fees and they just didn't know how to do it. Many things have happened since that time such as the operation of our special investigation unit, which takes about $600,000 a year. At the present time we are spending about $1,000,000 more than we are bringing in each year. Fiscal year 2011 we are projected to go into a deficit and now we feel its time to proceed with legislation to increase our licensing fees and other miscellaneous fees. We know this is a difficult environment to get this done right now. We are proposing a range to use so once this is passed, if we need to increase our fees again, it can be done through the regulatory process not through legislation. This is something that we have to do.

MOTION: DR. LUBKIN MOVED TO ADVANCE THIS PROPSED LANGUAGE FORWARD
SECOND: DR. TYLER SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED

Discussion

Mr. Conran stated that most licensing boards do have ranges to give them flexibility and to not have to go through legislation each time they need a fee increase.

Dr. Davis commented that he continues to be against some of the rates of increases. He feels some of them are not justifiable or warranted.

Judge Duvaras clarified that the revenue we receive is the only thing that operates this organization. We are never dependent on the general fund. He wonders if everyone is aware of this and feels this is important for the public to know how exactly how this organization is run and that its not based on the general fund or sales tax revenue, its all based upon fees collected.

Ms. Powell stated we have made some progress in getting the message out there. The Governor's office recognizes general fund agencies versus special fund agencies. Special fund agencies are not subject to lay-offs in the recent executive orders. We are subject to furloughs, but not lay-offs.

Proposed Regulations

A. Continuing Education

Dr. Tyler stated that the Continuing Education Committee, just like the Board, always tries to keep in mind the protection of the public.
We feel that continuing education should reflect our position to protect the public and to educate and re-educate our licensees so that they can become the finest doctors possible. We have had numerous work shops and meetings. What we have come up with may not be perfect and everyone will not love it, but it's a great start and hopefully is a benchmark for other boards to look at and say this is something they should look at and maybe even copy. He thanked Ms. Powell for her input, Mr. Stiger for his leadership of the staff, and Dr. Lubkin for crossing all the "T's and dotting all the "I"s. He is proud to be part of this committee.

Dr. Lubkin reiterated the outstanding job of all involved, we have put in hundreds of hours into this project. It is an excellent improvement from what we have.

MOTION: DR. LERNER MOVED TO ACCEPT THE AMMENDED REGULATORY CHANGES TO THE CONTINUING EDUCATION REGULATIONS
SECOND: DR. TYLER SECONDED THE MOTION
VOTE: 4-2
MOTION CARRIED

Discussion

Mr. Conran stated that he appreciates the amount of work that has been put into this. He recognized there's been a lot of hard work, however, he does not feel comfortable voting on all of this information. He is concerned about the issue that there is an exemption to licensees taking continuing education if they are on the Board. He cannot vote for something that exempts licensees who have to set the standard, although he knows the board wants to set the standard to the highest professional conduct. For the Board to exempt themselves from something every other licensee must do is not walking the talk. He recognizes that the Board did not put this in and that it is a pre-existing regulation, but he does feel he has to protest this. To his understanding no other licensing board in the state does this and he doesn't feel that we should do it.

Dr. Lerner commented that he would like to see a start date of January 1, 2010. He feels this is such a significant change that licensees have a chance to prepare for it.

Ms. Powell stated there can be two dates. One date can be for the providers having to comply with all the course previsions. The other date can be for the licensees. She suggested giving the licensees a full licensing cycle to do the increase in hours. If the Board votes to allow that, she and Mr. Stiger can plug in the dates since they can get tricky depending on how long it takes to get through the administrative process. She has some language from another board that may be helpful.

Judge Duvaras referred to page 4 and 5 regarding the mandatory categories. Judge Duvaras opposes the placement of adjustive techniques in an optional category. His feeling is that this should be in a mandatory class.

Judge Duvaras has been a chiropractic patient for a number of years, and he has talked to many chiropractors about the various techniques that have been brought into the chiropractic profession. If you go back as far as 1935 to the Palmer College of Chiropractic, where his father graduated from, the only technique was HIO, hole in one method, then other methods started coming into effect. There have been all types of techniques that have been brought about to try to improve the way a patient is adjusted to relieve him of a particular symptom and if that particular technique doesn't work maybe another technique would be more helpful. Judge Duvaras believes chiropractic manipulation is the basis of the profession.

This is what the chiropractic profession is all about, which is why he feels this particular subject should be put in the mandatory class.

Ms. Kristine Shultz, California Chiropractic Association, thanked the Board on drafting these regulations. They feel it's important to move this forward to the regulatory process now.

Dr. Davis feels this is a really good start and commends everyone that put this language together.

Dr. Ray Welch opposes 24 hours and mandatory manipulative therapy. He commented that the term chiropractic adjustive technique should be in the category that is mandatory. He provided the Board with detailed information of his concerns in an effort to remain brief in comments. He is in favor of a licensee who is unable to attend continuing education courses due to a physical disability and provides written certification from a primary health care provider may be exempted from completing continuing education requirements. He is concerned with the Executive Officer's decision being the final order in a denial, he feels if the Executive Officer's decision is based on a chiropractic issue and not a legal one, then the appointed board should be consulted. He understands the rational of no more than 8 hours of instruction shall be given during a 24 hour period. He feels this puts an additional financial burden on the DCs and that there should be no issues with attending a 12 hour seminar. He has been doing 12 hour seminars since 1994. Regarding class breaks being at the discretion of the instructor and breaks shall not count toward a course hour. He doesn't feel this protects the public, only hurts the DC.

Dr. Lubkin responded to Dr. Welch's comments indicating that he was reading from on old version of the language. There is updated language that satisfies some of Dr. Welch's concerns.

Kendra Holloway, Life Chiropractic College West, they just now received the latest copy of the proposed language and has provided some comments to Mr. Stiger on the December 18th draft. There are some major issues on clarity, necessity and consistency with existing law. There are also conflicts such as in order to renew an inactive license, the licensee must complete all the years of being inactive, however, the Business and Professions code says the licensee only has to do one. She reads this from the point of an end user, a CE provider and as a licensee, and has trouble reading it. She feels that this needs to go back to the work group so it can be cleaned up to be something everyone can understand.

Dr. Sherry McAllister, thanked the board for the work that has been done. She commented that at the last board meeting Ms. Scurri stated that the language had some refining to do and feels this new document has made some improvements. She would like to support Dr. Holloway's remarks for the possibility that this respectfully be returned to the work group. She feels this would be an excellent idea.

Dr. George Casey, Life Chiropractic College West, asked for clarification on if the Board approves it at this point, what are the time lines and steps that will occur for continued public comment.

Mr. Stiger responded once the document is filed with the Office of Administrative Law, there is a 45 day comment period. There is also another 15 days and comments may even be submitted now.

B. Fingerprinting of Applicants and Licensees

Ms. Powell stated that all boards have not always fingerprinted licensees, and since Live Scan technology came into being in about 1999, we now have a better process for fingerprinting and also subsequent arrest information. Some issues have been raised with other boards who have licensees who are not fingerprinted, or who were fingerprinted, but DOJ doesn't have a record of the fingerprint. The licensee gets arrested and the board not knowing until a newspaper article comes out and this is just not acceptable for consumer protection. This proposed regulation would give the board specific authority to fingerprint. Although we already have it under the penal code, the FBI doesn't like the way our language reads, so in order to continue to get FBI information we need to update the language to have our own stand alone regulation.

MOTION: MR. CONRAN MOVED TO PROGRESS THE PROPOSED REGULATION OF FINGERPRINTING APPLICANTS AND LICENSEES FORWARD
SECOND: DR. LUBKIN SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED

C. Chiropractic Specialties

Dr. Lerner stated that this went from 4 pages to 8 pages and the overall feedback was that it's much to complex. It's now down to one sentence and he can't imagine a more simplified regulation.

Ms. Powell stated it's different but she wants to clarify that it's simple because it specifies who the board recognizes however, it does not address advertising at all. It is merely what specialties the board recognizes and that is important, we narrowed it down to address the actual problem.

Dr. Lerner read the language, "The board recognizes those specialty programs that are recognized by the American Chiropractic Association, the International Chiropractors Association, and equivalent specialty programs as determined by the board."

MOTION: DR. LUBKIN MOVED TO PROGRESS THE PROPOSED REGULATION OF CHIROPRACTIC SPECIALTIES FORWARD
SECOND: DR. COLUMBU SECONDED THE MOTION
VOTE: 6-0
MOTION CARRIED

Discussion

Ms. Shultz is in support of the changes and said it looks really good.

Dr. Davis stated it looks much better than what we saw in November, it's a great improvement.

D. Proposed Regulations Regarding Time Frame to Petition for Reinstatement of a License and Modification of Probation or Early Termination of Probation

Mr. Stiger clarified that this was approved by the board back in November and this is only an update that we are project to file this regulation with OAL on February 3, 2009, so the 45 day comment period should be February 13 through March 30 and we are looking at a scheduled public hearing on March 31, 2009 here in Sacramento.

E. Manipulation Under Anesthesia

Mr. Stiger stated the Ms. April Alameda filed the MUA regulations with OAL on December 30. The 45 day comment period is from January 9 through February 23 and we are scheduled for a public hearing on February 24, 2009 here in Sacramento.

F. Letter of Admonishment

Mr. Stiger stated we are waiting on the Department of Finance to approve our Economic Impact Statement. Once that document is approved we can move on to the final phases.

G. Repeal of Quality Review Panels

Mr. Stiger stated we just received verbal approval from the Department of Finance on December 29. They approve out Economic Impact Statement and it's been filed with OAL on January 6.

Public Comment

None

Future Agenda Items

Dr. Tyler is concerned about where the future meeting will be held.

Dr. Lerner stated something that he feels fell through the cracks, chiropractic consultant position, he believes we were suppose to look at this and would like some idea of where we are at and if we should take further action or not.

Mr. Conran feels we need to develop a policy of disposing of confidential documents and not leave it up to the discretion of board members. He had an experience where he walked into a room to do a presentation and a previous board had left confidential documents on the table. Although this board has not done that, he feels there is a need for security within our administrative procedure manual so board members have clear direction to ensure this doesn't happen. His policy is to hand it to board staff, but we should have a policy to practice.

Judge Duvaras suggested a topic on petition hearing. Specifically, he feels that all of the petition hearings should be held in Sacramento. Past history is shown is more costly to bring documentation and staffing. Petitions for hearing, with proper notice should be held here

Dr. Lubkin would like to see us continue to work on the seal.

Dr. Davis commented he would like to retire from video recording responsibility.

Hearings re: Petition for Reinstatement of Revoked License

Administrative Law Judge Catherine B. Frink presided over and Deputy Attorney General Tom Rinaldi appeared on behalf of the people of the State of California on the following hearings.

- Todor P. Azgorov
- Robert L. Horan
- David L. Hagen

Following oral testimonies, the Board went into closed session to consider Charles Whitney and Todor Azgorov for reinstatement of Revoked License.

Closed Session

Following oral testimonies, the Board went into closed session for deliberation and determinations of Petitioners.

Adjournment

Dr. Lerner adjourned the public meeting at 3:55 p.m.

Attachment A

Approval By Ratification of Formerly Approved License Applications
November 14, 2008 – December 22, 2008

Name (First, Middle, Last)			Date Issued	DC#
Daniel	William	Gambino	11/26/2008	**31087**
Se Jun		Li	11/26/2008	**31088**
Lance	Kelly	McKnight	11/26/2008	**31089**
Alex	Wing	Tam	11/26/2008	**31090**
Hsuan		Wang	11/26/2008	**31091**
Alan	T.	Zee	11/26/2008	**31092**
Scott	David	Nissenbaum	12/12/2008	**31093**
Ami	Gitesh	Shah	12/12/2008	**31094**
Joon	Hyung	Song	12/12/2008	**31095**
Gregory	Philip	Vrankovich	12/12/2008	**31096**
Joshua	Michael	Welch	12/22/2008	**31097**

Attachment B

Ratification of Formerly Denied License Applications
Applicants Did Not Submit an Appeal

September 12, 2006 – December 31, 2008

Name (First, Middle, Last) **Date Denied**
Reason for Denial

Primes, Tikisa LaRue **10/13/2006**
Criminal Convictions:
- Possession or Purchase of cocaine base for sale - Felony
- Possession for sale of marijuana - Felony

Roach, Erik Douglas **09/12/2006**
Criminal Convictions:
- Driving while intoxicated - Misdemeanor
- Driving while intoxicated - Misdemeanor

Probationary License Offered
Applicant Declined Probationary License

Sterling, Michael **03/22/2007**
Criminal Convictions:
- Driving while intoxicated - Misdemeanor
- Driving while intoxicated - Misdemeanor

Answered Dishonestly on Application

Waggoner, Shaeli **06/22/2007**
Criminal Convictions:
- Driving while intoxicated - Misdemeanor
- Possession of Controlled Substance - Felony

FUND NO. 0152
Expense Index
As of
January 31, 2009

BOARD OF CHIROPRACTIC EXAMINERS
BUDGET REPORT
EXPENDITURE PROJECTION

MONTH 7 — Mos. Remaining: 5

OBJECT DESCRIPTION	FY 2008-09 BUDGET ALLOTMENT	CY EXPENDITURES AS OF 1/31/09	PERCENT OF BUDGET SPENT	PROJECTIONS TO YEAR END	UNENCUMBERED BALANCE
PERSONAL SERVICES:					
Salaries and Wages					
Civil Service-Perm	926,393	484,506	52.3%	926,393	0
Temp Help (907)	0	23,916	0.0%	60,000	(60,000)
Board/Commission (910,920)	16,000	4,800	30.0%	9,000	7,000
Overtime (909)	4,615	0	0.0%	0	4,615
Staff Benefits	389,158	170,911	43.9%	367,966	21,192
Salary Savings	(1,219)	0	0.0%	0	(1,219)
TOTAL, PERSONAL SVC	1,334,947	684,133	61.6%	1,363,359	(28,412)
OPERATING EXPENSE AND EQUIPMENT:					
General Expense	52,000	5,211	10.0%	20,000	32,000
Printing	7,331	789	10.8%	5,000	2,331
Communication	61,136	12,877	21.1%	28,000	33,136
Postage	11,662	1,970	16.9%	20,000	(8,338)
Travel In State	21,241	23,612	111.2%	40,000	(18,759)
Travel, Out-of-State	24,121	415	1.7%	18,000	6,121
Training	13,331	13,466	101.0%	15,000	(1,669)
Facilities Operations	140,754	64,498	45.8%	112,000	28,754
C & P Services - Interdept.	57,384	15,878	27.7%	123,000	(65,616)
C & P Services - External	124,513	19,946	16.0%	270,000	(145,487)
DP Billing (OIS) Prorata	6,936	0	0.0%	0	6,936
Consolidated Data Center	25,985	12,662	48.7%	27,000	(1,015)
Interagcy Agreement IT	51,723	0	0.0%	108,000	(56,277)
NOC Serv IT (Security)	63,881	9,958	15.6%	0	63,881
IT Consultant	54,136	0	0.0%	0	54,136
DP Supplies	0	2,152	0.0%	0	0
Central Admin Pro Rata	126,458	63,229	50.0%	126,458	0
Administrative External Svcs	0	844	0.0%	0	0
Major Equipment	85,000	0	0.0%	66,000	19,000
Minor Equipment	50,000	3,389	6.8%	10,000	40,000
Vehicle Operations	6,000	426	7.1%	6,000	0
ENFORCEMENT:					
Attorney General	941,000	175,583	18.7%	941,000	0
Attorney General Fingerprinting	10,000	1,770	17.7%	5,000	5,000
Office Admin. Hearing	217,379	29,637	13.6%	217,379	0
Evidence / Witness Fees	75,000	15,547	20.7%	75,000	0
Consultant Investigations	40,754	0	0.0%	0	40,754
Div. of Investigations	0	0	0.0%	0	0
Special Adjustments	0	0	0.0%	0	0
TOTALS, OE&E:	2,267,725	473,859	20.9%	2,232,837	34,888
TOTAL EXPENSE:	3,602,672	1,157,992	32.1%	3,596,196	6,476
Sched. Reimb. - Other	(33,000)	0	0.0%	(5,000)	(28,000)
Sched. Reimb. - Fingerprints	(11,000)	0	0.0%	0	(11,000)
Unsched. Reimb.	0	0	0.0%	0	0
TOTAL REIMBURSEMENTS:	(44,000)	0	0.0%	(5,000)	(39,000)
NET APPROPRIATION:	**3,558,672**	**1,157,992**	**32.5%**	**3,586,196**	**(32,524)**
			SURPLUS/(DEFICIT):		**-0.91%**

Revised March 5, 2009

Recruitment and Selection of Vacant Position Update
March 16, 2009

Classification	Date Advertised	Application Review	Interviews Conducted	Background Checks	Formal Offer	Start Date
Spec. Investigator (Southern California)	1/23/09	Completed	Completed	Completed	3/13/09	4/1/09
Spec. Investigator (Southern California	1/23/09	Completed	Completed	In Progess		
Staff Services Manager I	2/5/09	Completed	Completed	Completed	2/17/09	3/18/09

BOARD OF CHIROPRACTIC EXAMINERS
LICENSE STATISTICAL DATA

FY 2007/08 – FY 2008/09 COMPARISON

LICENSE TYPE	TOTAL LICENSES 2/29/2008	TOTAL LICENSES 2/28/2009	NET VARIANCE
CHIROPRACTORS	13,833	13,801	-32
SATELLITES	2,237	2,597	+360
CORPORATIONS	1,296	1,307	+11
REFFERALS	17	18	+1
TOTALS	17,383	17,723	+340

Applications Received and Processed

JANUARY 1, 2009 – FEBRUARY 28, 2009

APPLICATION TYPE	RECEIVED	APPROVED	DENIED	WITHDRAWN	PENDING
INITIAL	106	87	3	0	148
RECIPROCAL	4	1	0	0	17
RESTORATION	12	4	1 – Non Qualify	1	9
CORPORATION	37	23	0	0	25

Compliance Unit Statistics

Fiscal Year	05/06	06/07	07/08	08/09*
Complaints				
Received	762	701	644	405
Pending	755	864	818	658
Closed with Insufficient Evidence	116	131	106	117
Closed with No Violation	96	60	78	122
Closed with Merit	319	200	321	133
Citations and Fines Issued (Total Fine Amount)	36	34	28	20 ($8,250)
Accusations				
Filed	45	42	13	24
Revoked	15	27	8	4
Revocation Stayed: Probation	16	23	10	3
Revocation Stayed: Suspension and Probation	15	15	10	3
Suspension	0	1	0	0
Voluntary Surrender of License	8	4	2	1
Dismissed/Withdrawn	0	3	3	2
Statement of Issues				
Filed	5	11	7	3
Denied	0	1	0	0
Probationary License	0	0	0	0
Withdrawn at Applicant's Request	0	2	1	0
Granted	8	3	0	0
Petitions				
Reconsideration				
Filed	1	1	0	0
Granted	1	0	0	0
Denied	0	1	0	0
Reinstatement of License				
Filed	9	8	9	2
Granted	1	2	0	4
Denied	9	3	5	5
Early Termination of Probation				
Filed	2	5	4	5
Granted	1	4	1	2
Denied	1	0	1	4
Modification of Probation				
Filed	1	0	0	0
Granted	1	0	0	0
Denied	0	0	0	0
Probation Cases				
Active	188	173	159	139

* FY 08/09: July 1, 2008 – February 28, 2009

Revised: March 2, 2009

Violation Codes/Descriptions

The Chiropractic Initiative Act of California (ACT):

10 – Rules of Professional Conduct
15 – Noncompliance With and Violations of Act

California Code of Regulations (CCR):

302(a) – Scope of Practice
303 – Filing of Addresses
304 – Discipline by Another State
308 – Display of License
311 – Advertisements
312 – Illegal Practice
316 – Responsibility for Conduct on Premises
317 – Unprofessional Conduct
318 – Chiropractic Patient Records/Accountable Billing
319 – Free or Discount Services
355 – Renewal and Restoration
360 – Continuing Education Audits
367.5 – Application, Review of Refusal to Approve (corporations)
367.7 – Name of Corporation

Business and Professions Code (BP):

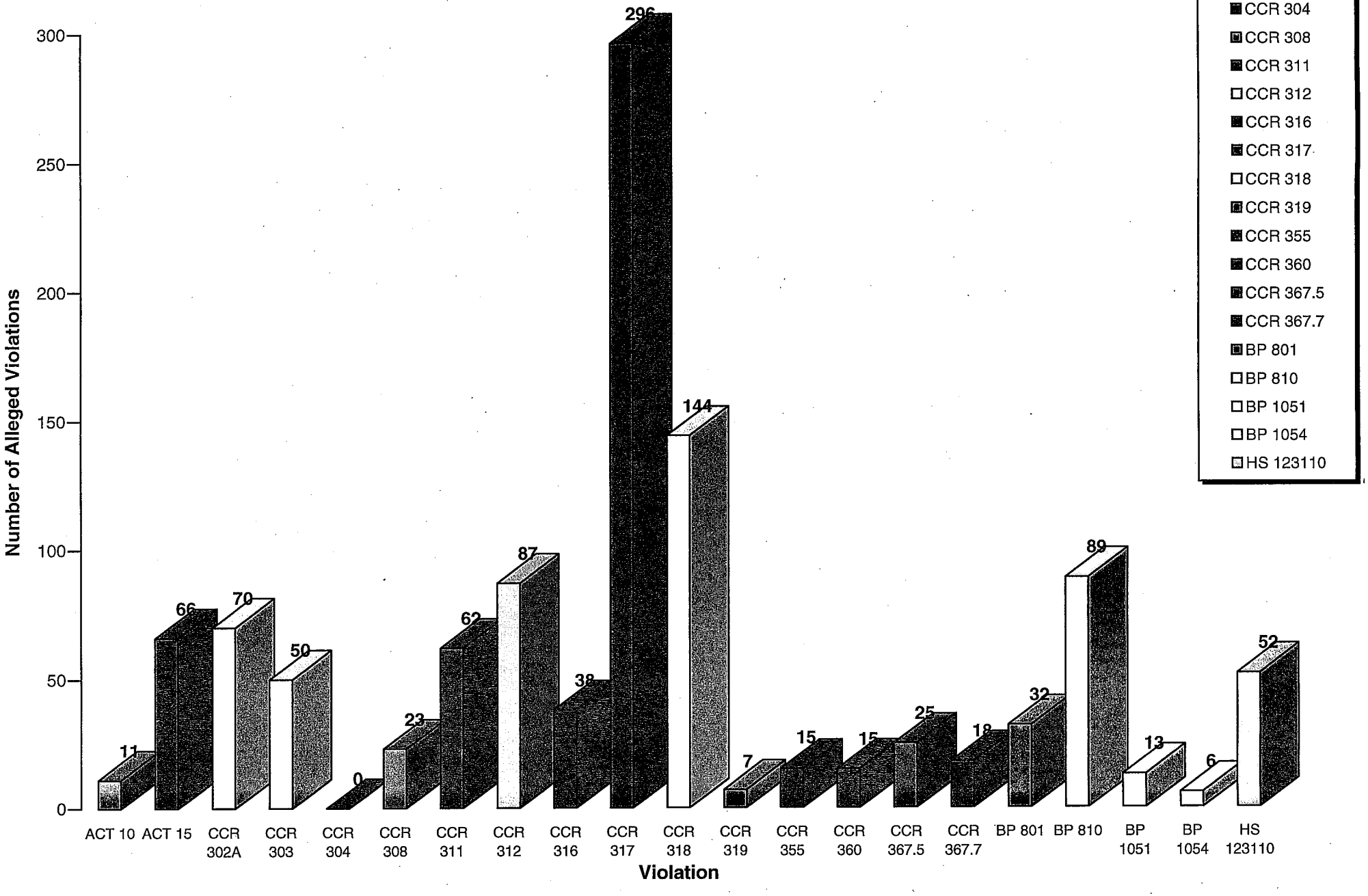
801 – Professional Reporting Requirements (malpractice settlements)
810 – Insurance Fraud
1051 – Apply for a Corporation with the Board
1054 – Name of Chiropractic Corporation

Health and Safety Code (HS):

123110 – Patient Access to Health Records

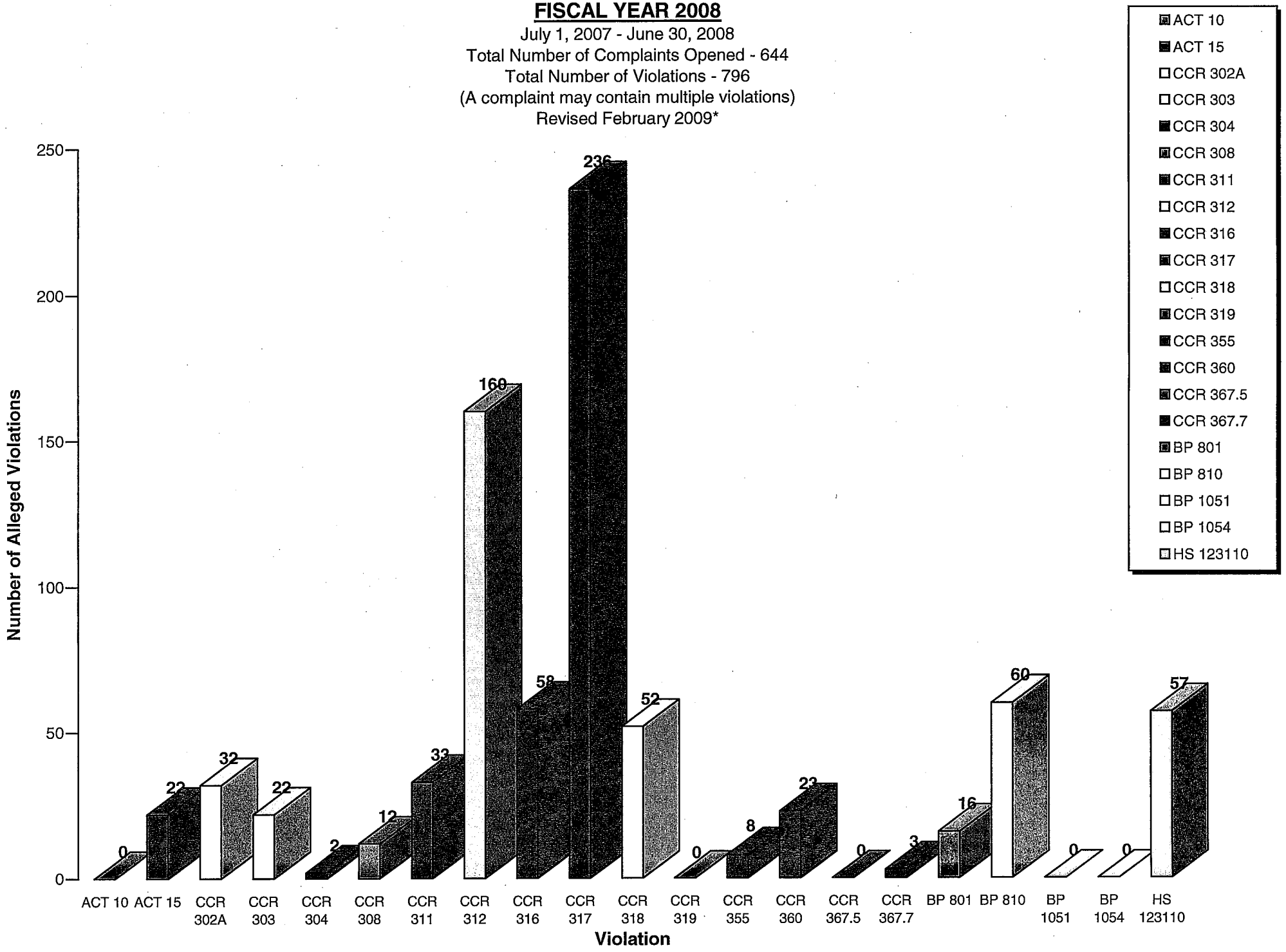
FISCAL YEAR 2007

July 1, 2006 - June 30, 2007
Total Number of Complaints Opened - 701
Total Number of Violations - 1129
(A complaint may contain multiple violations)
Revised February 2009*



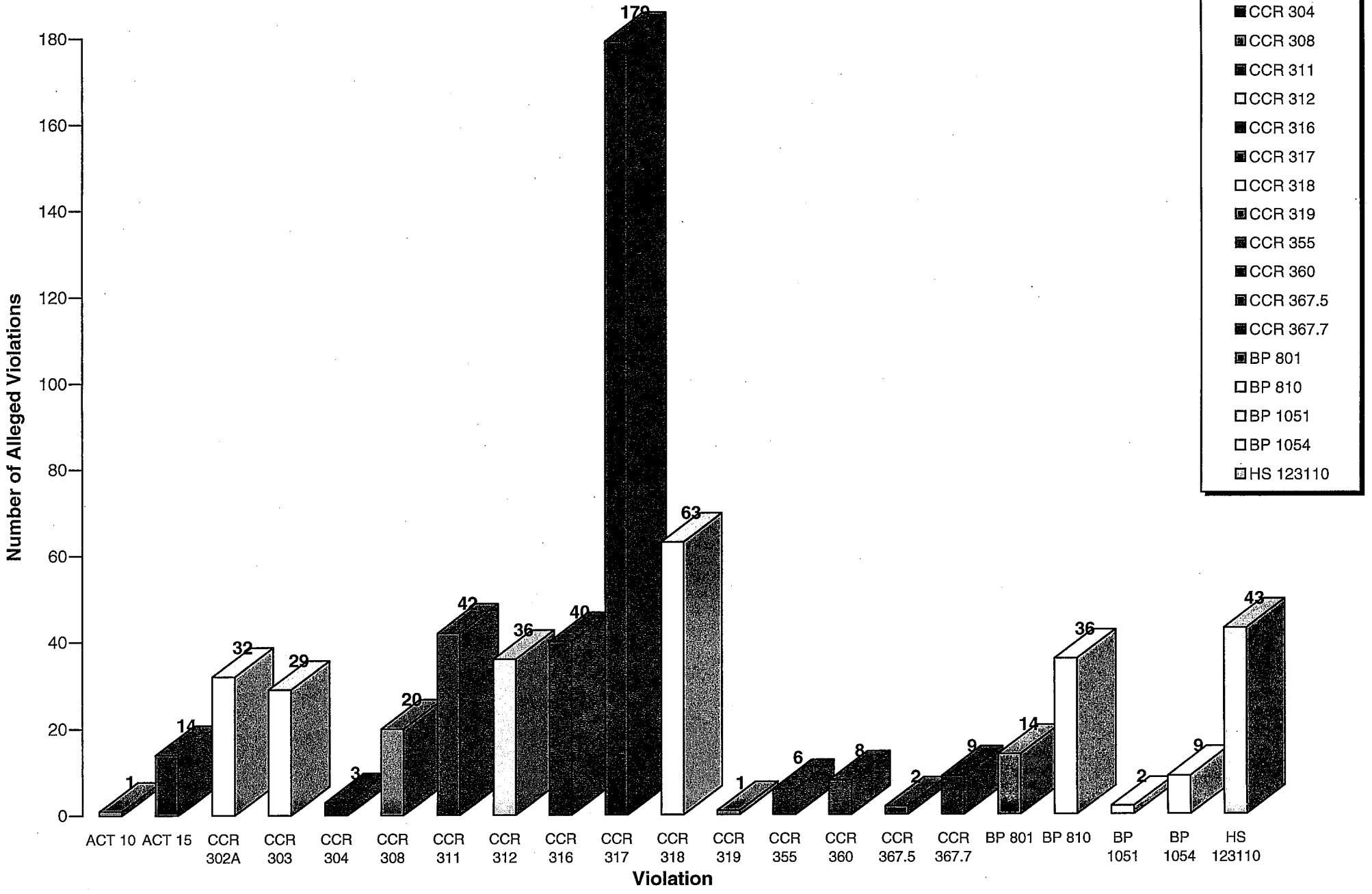
FISCAL YEAR 2008

July 1, 2007 - June 30, 2008
Total Number of Complaints Opened - 644
Total Number of Violations - 796
(A complaint may contain multiple violations)
Revised February 2009*



FISCAL YEAR 2009

July 1, 2008 - February 28, 2009
Total Number of Complaints Opened - 405
Total Number of Violations - 589
(A complaint may contain multiple violations)



Board of Chiropractic Examiners
Audio-Video Web Casting
March 16, 2009

Equipment	Cost	Status
Video Camera	$ 606.05	Purchased – 3/16/09
Tripod (for Camera)	$ 27.48	Purchased – 3/16/09
Microphone Stereo Mixer	$ 221.49	Purchased – 3/17/09
Microphones	$ 813.64	Purchased – 3/17/09
Cable Connection	$ 7.12	Purchased – 3/17/09
Microphone Extension Cables	$ 95.73	Purchased – 3/17/09

Total Equipment Cost: **$1, 771.51**

Contract	Cost	Status
Software/Equipment	$ 5,362.50	Final Bids Received – 3/16/09 Pending – signature of contract
Monthly Services (1 year)	$ 5,850.72	Final Bids Received – 3/16/09 Pending – signature of contract

Total Contract Cost: **$ 11,213.22**

Total Cost for FY 08/09 **$ 12,984.73**

Total Cost for FY 09/10 and on-going **$ 5,850.72**

Status of Bureau of State Audits Recommendations
Chapter 1
March 1, 2009

BSA Audit Recommendations	Fully Implemented	Partially Implemented	Estimated Completion Date
To ensure that it complies with all Bagley-Keene requirements, the chiropractic board should: • Continue to involve legal counsel in providing instruction and training to board members at each meeting. • Continue to retain documentation of the steps it takes to publicly announce its meetings.	X X		
To ensure that the chiropractic board complies with administrative procedure act requirements, board members should ensure they limit their communications related to board business so they do not engage in ex parte communications or compromise their ability to fulfill their responsibility in enforcement hearings.	X		
To ensure compliance with the initiative act, the chiropractic board should modify its current process so that board members make the final decision to approve or deny all licenses. Additionally, board members should ratify the previous license decisions staff made.	X		
To comply with the political reform act, the chiropractic board should do the following: • Ensure that its filing official is aware of the role and responsibilities and similarly, promptly inform anyone replacing the filing official. • Establish an effective process for tracking whether all designated employees, including board members, have completed and filed their statements of economic interests on time, to identify potential conflicts of interest. • Periodically review its employees' responsibilities to ensure that all individuals who are in decision-making positions are listed as designated employees in its conflict-of-interest code.	X X X		

Status of Bureau of State Audits Recommendations
Chapter 1 (Cont.)
March 1, 2009

BSA Audit Recommendations	Fully Implemented	Partially Implemented	Estimated Completion Date
The chiropractic board should consider providing state e-mail accounts to its board members so they conduct their chiropractic board business in a secure and confidential environment and make their actions and correspondence accessible under public records act requests.	X		
To ensure that they continue to improve their knowledge and understanding of Bagley-Keene, other state laws, and board procedures, board members should continue to use their newly adopted administrative manual as guidance for conducting board business.	X		
To ensure that it complies with Bagley-Keene requirements and state laws requiring board members to attend training within specific time frames, and to ensure board members receive orientation within a reasonable amount of time of assuming office, the chiropractic board should: • Ensure staff retain documentation when they provide a copy of the Bagley-Keene to each board member. • Continue to use the member appointment checklist and establish procedures to periodically record and monitor board member training. • Continue the practice of sending new board members to the orientation that Consumer Affairs provides.	X	 X X	 Upon appointment Upon appointment

Status of Bureau of State Audits Recommendations
Chapter 2
March 1, 2009

BSA Audit Recommendations	Fully Implemented	Partially Implemented	Estimated Completion Date
To ensure that it has adequate controls over its complaint review process, the chiropractic board should do the following:			
• Develop procedures to ensure that the chiropractic board processes and resolves complaints as promptly as possible by establishing benchmarks and more structured policies and procedures specific to each step in its complaint review process.	X		
• Establish time frames for staff to open complaint cases, complete initial review, refer cases to an investigator or expert if necessary and close or otherwise resolve complaints through implementing informal discipline or referring for formal discipline to ensure that all complaint cases move expeditiously through each phase of the complaint review process.	X		
• Periodically review the status of all open complaints and investigations and identify and resolve any delays in processing.	X		
• Strengthen its enforcement policies and procedures to minimize the amount of time it takes staff to process consumer complaints before forwarding them to the attorney general or other law enforcement agency to ensure that it adequately assists attorneys and law enforcement agencies in enforcing the laws of chiropractic.	X		
To ensure that its enforcement procedures are complete and provide adequate guidance to enforcement staff, the chiropractic board should do the following:			
• Develop policies and procedures requiring that only a manager or a designated employee are allowed to make the final decisions on complaint resolution.	X		
• Develop procedures to ensure that staff reports the issuance of citations to other states' chiropractic boards and regulatory agencies.	X		
• Develop procedures instructing staff when to open and how to process complaints generated internally.	X		

Status of Bureau of State Audit Recommendations
Chapter 2 (Cont.)
March 1, 2009

BSA Audit Recommendations	Fully Implemented	Partially Implemented	Estimated Completion Date
To ensure that it processes and resolves consumer complaints regarding the same allegations consistently and that it consistently processes consumer complaints according to its enforcement policies and procedures, the chiropractic board should strengthen its existing procedures to provide guidance for staff on how to process and resolve all types of complaints and to ensure appropriate management oversight.	X		
To ensure that its processes for prioritizing consumer complaints are adequate and effective to ensure that staff clearly identify and process priority complaints promptly, the chiropractic board should do the following: • Implement tracking methods, such as flagging priority cases during complaint intake, using multiple levels of priority categories, and assigning specific time frames to process those priority categories. • Establish procedures that direct board management to monitor the status of open complaints regularly especially those given priority status, to ensure that they do not remain unresolved longer than necessary.	X X		
To ensure that it is in compliance with all of its regulations, the chiropractic board should carefully consider the intended purpose of the quality review panels and whether implementing them is the best option to fulfill that intent. If the chiropractic board decides that another option would better accomplish the intended purpose of the quality review panels, it should implement the process for revising its regulations.	X		
To ensure that it has necessary resources to answer technical questions regarding quality of care and improper treatment that often arise, the board should fill and maintain its chiropractic consultant position. In addition, the board should ensure that its chiropractic consultant acts only in an advisory capacity and that the executive officer makes the final decision.	Alternative resolution is fully implemented.		

Status of Bureau of State Audits Recommendations
Chapter 2 (Cont.)
March 1, 2009

BSA Audit Recommendations	Fully Implemented	Partially Implemented	Estimated Completion Date
To ensure that it adequately controls the use of experts, the chiropractic board should do the following: • Establish policies and procedures requiring its staff to document interviews with experts, including the content of those discussions to ensure that it refers cases to qualified experts who are free of conflicts. • Consider entering into formal written contracts for services from experts or require them to provide written attestations that they are free of conflicts in cases assigned. • Strengthen its policies and procedures to ensure that its staff monitors experts on their adherence to the established 30-day deadline for reviewing complaint cases and submitting a written report. • Consistently perform an evaluation of the expert's written report and thoroughly document the results of the evaluations to ensure that it does not inappropriately refer complaint cases to experts who have not demonstrated quality work in the past.	X		05/01/09 05/01/09 05/01/09
To ensure that the chiropractic board can demonstrate that its employees meet the minimum qualifications for their positions, it should retain personnel documentation on all employees according to record retention policy. In addition, the chiropractic board should require its personnel contractor to comply with the same requirements.	X		
To ensure that future chiropractic consultants are hired with the desired qualifications, the board should consider revising the position's minimum qualifications to provide additional clarity on the term practice of chiropractic, similar to the board's current requirements for experts.			12/31/09

Status of Bureau of State Audits' Recommendations
Chapter 3
March 1, 2009

BSA Audit Recommendations	Fully Implemented	Partially Implemented	Estimated Completion Date
To ensure that it is able to measure the overall efficiency of its licensing program in processing applications and petitions, the chiropractic board should do the following: • Establish time frames for all types of applications and petitions the board processes. • Establish a tracking system for applications and petitions to analyze where delays are occurring and ensure that applications and petitions are processed promptly. • Establish a time frame for resolving appeals that includes milestones for each phase of the process.	X X X		
To ensure that it only licenses those who are committed to following its laws and regulations, the chiropractic board should develop specific policies and procedures for staff to follow when the board has received a complaint against an applicant seeking licensure.	X		
To ensure that the chiropractic board is able to defend its decisions on approved applications for satellite offices, corporations, and referral services, it should implement a standard of required documentation that includes identifying when and who conducted eligibility verifications.	X		
To ensure that it is placing licenses on forfeiture status according to the initiative act, the chiropractic board should do the following: • Establish specific procedures for staff to follow when licensees submit invalid payment when renewing licenses. • Establish a tracking method to ensure that requests for repayment are sent promptly	X X		

Status of Bureau of State Audits Recommendations
Chapter 3 (Cont.)
March 1, 2009

BSA Audit Recommendations	Fully Implemented	Partially Implemented	Estimated Completion Date
To ensure that the chiropractic board's continuing education program complies with current regulations, it should do the following:			
• Have board members ratify staff approvals of continuing education providers.	X		
• Ensure its process to approve continuing education providers conforms with its regulations.	X		
• Comply with requirements for notifying providers of board member approval within two weeks following a scheduled board meeting and for notifying providers of application deficiencies within three weeks of receiving the application.		X	04/01/09
• Establish a process to track and monitor whether continuing education providers submit attendance rosters within 60 days of course completion.	X		
• Establish a procedure for maintaining accurate documentation of continuing education audits of licensees.	X		
• Establish a mechanism to ensure that all relevant steps are taken before continuing education audits are considered complete.	X		
• Establish a process to track course audits conducted and a procedure for taking corrective action when the course reviewer identifies a deficiency.	X		

SPEC: CHIROPRACTIC CONSULTANT, BOARD OF CHIROPRACTIC EXAMINERS
CALIFORNIA STATE PERSONNEL BOARD

SPECIFICATION

Schematic Code:	EV20
Class Code:	9964
Established:	4/18/95
Revised:	--
Title Changed:	--

CHIROPRACTIC CONSULTANT, BOARD OF CHIROPRACTIC EXAMINERS

DEFINITION

Under general direction, to serve as a consultant to the Board, its staff, and the Chiropractic Quality Review Panels regarding the professional competence of chiropractors; to provide chiropractic expertise in the review of chiropractic investigations and evaluations of the professional conduct of licensees in relation to the requirements of the law; to assist in the preparation of administrative or court actions by providing chiropractic expertise; to serve as an expert witness; to monitor probationers of the Board; and to do other related work.

TYPICAL TASKS

A Chiropractic Consultant, Board of Chiropractic Examiners, makes recommendations based on the review of complaints against chiropractors to assure compliance with laws relating to professional and individual competence; consults with the Executive Secretary in the preparation of evidence for presentation before the Board of Chiropractic Examiners and Chiropractic Quality Review Panels; consults with the Attorney General's Office Review Panels; consults with the Attorney General's Office in the preparation of legal actions; assists in the interview of witnesses and interested parties to secure information relating to chiropractic practices; interprets the chiropractic significance of information and evidence; makes recommendations regarding and assists in obtaining information and evidence which requires the immediate knowledge of professional chiropractic to secure; conducts audits of chiropractic office records to determine if the records, x-ray, and laboratory findings support the actual diagnosis and treatments performed, and to assure compliance with staff, organization, and record-keeping provisions of the Business and Professions Code; confers with and obtains the cooperation of recognized chiropractic consultants concerning the specialized practices of chiropractic and special or unusual chiropractic procedures and techniques; represents the Board before professional or lay groups; assists investigators and office staff in monitoring activities and performance of licensees who have been placed on probation by the Board; and prepares and dictates correspondence.

MINIMUM QUALIFICATIONS

Possession of a valid license for the practice of chiropractic in California as determined by the California Board of Chiropractic Examiners.

and

Experience: Five years of experience, within the last seven years, in the practice of chiropractic.

KNOWLEDGE AND ABILITIES

Knowledge of: Chiropractic, including recent developments and practices; record-keeping practices; provisions of the Business and Professions Code relating to the practice of chiropractic and the laws, rules and regulations of the Board of Chiropractic Examiners relating to chiropractic practice and continuing education; chiropractic specialties; principles, aims, methods and trends of contemporary chiropractic education; administration, curriculum, and procedures of providers of continuing education services.

Ability to: Conduct effective interviews; exercise sound chiropractic judgment in reviewing conflicting chiropractic reports and preparing opinions; analyze problems and recommend effective action; dictate correspondence; prepare reports; communicate effectively.

SPECIAL PERSONAL CHARACTERISTICS

Demonstrated ability to work cooperatively with others; emotional stability; integrity; initiative; good judgment; dependability; tact; courtesy; high professional ethics; willingness to travel throughout the State.

STATE OF CALIFORNIA

DUTY STATEMENT

GS 907T (REV. 1/98)

DEPARTMENT OF GENERAL SERVICES

SHADED AREA FOR HUMAN RESOURCES ONLY

INSTRUCTIONS: Refer to the Payroll and Personnel Procedures Manual (PPPM) for Duty Statement Instructions.

RPA-	EFFECTIVE DATE:
006-CHIRO	

1. DGS OFFICE OR CLIENT AGENCY	POSITION NUMBER (Agency - Unit - Class - Serial)
Board of Chiropractic Examiners	- - -
2. UNIT NAME AND CITY LOCATED	3. CLASS TITLE
Chiro Administration - Sacramento	CHIROPRACTIC CONSULTANT
4. PROPOSED INCUMBENT (If known)	5. CURRENT POSITION NUMBER (Agency - Unit - Class - Serial)

6. BRIEFLY (1 or 2 sentences) DESCRIBE THE POSITION'S ORGANIZATIONAL SETTING AND MAJOR FUNCTIONS

Under the supervision of the Executive Director, the Chiropractic Consultant reviews and evaluates complaints of professional misconduct against licensees. This includes interpreting the chiropractic significance of information and evidence. Specific tasks include, but are not limited to the following:

7. Percentage of time performing duties	8. Indicate the duties and responsibilities assigned to the position and the percentage of time spent on each. Group related tasks under the same percentage with the highest percentage first. *(Use additional sheet if necessary)*
	ESSENTIAL FUNCTIONS
40%	Provide chiropractic expertise in the review of complaints and evaluations of the professional conduct of licensees in relation to possible violations of the laws and regulations. Respond in writing or by phone to consumers and other governmental or private entities' inquiries and complaints. Answer complex questions pertaining to practice issues and procedures.
25%	Review investigation reports to determine if sufficient evidence exists for administrative action or if further investigation is needed. Consult with deputy attorney general in preparation of administrative actions.
5%	Attend Board meetings to present items of interest relating to enforcement or examination issues.
5%	Prepare regulation language for review and discussion by the Regulation Review Committee.
5%	Review Chiropractic Law and Professional Practices Examination questions for accuracy, and serve as lead consultant in test question development.
5%	Confer with and obtain the cooperation of recognized chiropractic consultants concerning the specialized practices or chiropractic and special or unusual chiropractic procedures and techniques.
5%	Review complaint case to determine if a citation should be issued.
5%	Assist in the review and recommendations for continuing education courses.

9. SUPERVISOR'S STATEMENT: *I HAVE DISCUSSED THE DUTIES OF THE POSITION WITH THE EMPLOYEE*

SUPERVISOR'S NAME (Print)	SUPERVISOR'S SIGNATURE	DATE

10. EMPLOYEE'S STATEMENT: *I HAVE DISCUSSED WITH MY SUPERVISOR THE DUTIES OF THE POSITION AND HAVE RECEIVED A COPY OF THE DUTY STATEMENT*

EMPLOYEE'S NAME (Print)	EMPLOYEE'S SIGNATURE	DATE

5%

NON-ESSENTIAL FUNCTIONS

Perform other duties as assigned by the Executive Director.

KNOWLEDGE AND ABILITIES

Knowledge of:
Chiropractic, including recent developments and practices; record-keeping practices; provisions of the Business and Professions Code relating to the practice or chiropractic and the laws, rules and regulations of the Board of Chiropractic Examiners relating to chiropractic practice and continuing education; chiropractic specialties; principles, aims, methods and trends of contemporary chiropractic education; administration, curriculum, and procedures of providers of continuing education services.

Ability to:
Conduct effective interviews; exercise sound chiropractic judgment in reviewing conflicting chiropractic reports and preparing opinions; analyze problems and recommend effective action; dictate correspondence; prepare reports; communicate effectively.

DESIRABLE QUALIFICATIONS

SPECIAL PERSONAL CHARACTERISTICS
- Demonstrated ability to work cooperatively with others;
- Emotional stability;
- Integrity;
- Use good judgment and takes effective action
- Dependability and tact;
- Use courtesy;
- High professional ethics;
- Willingness to travel throughout the State.

ADDITIONAL QUALIFICATIONS
- Experience in writing procedures, manuals, and reports
- Proficiency with Microsoft Word, Outlook, Excel, Teale Data System, and Access
- Good organizational skills

WORK ENVIRONMENT, PHYSICAL OR MENTAL ABILITIES

Frequent off-site meetings
Occasional local and statewide travel, often independently
Requires presentations to professional audience
Effectively handle stress, frequent deadlines, and changing priorities
Frequent use of a personal computer and/or laptop and related software applications at a workstation

11. SUPERVISOR'S STATEMENT: *I HAVE DISCUSSED THE DUTIES OF THE POSITION WITH THE EMPLOYEE*

SUPERVISOR'S NAME (Print)	SUPERVISOR'S SIGNATURE	DATE

12. EMPLOYEE'S STATEMENT: *I HAVE DISCUSSED WITH MY SUPERVISOR THE DUTIES OF THE POSITION AND HAVE RECEIVED A COPY OF THE DUTY STATEMENT*

The statements contained in this duty statement reflect general details as necessary to describe the principal functions of this job. It should not be considered an all-inclusive listing of work requirements. Individuals may perform other duties as assigned, including work in other functional areas to cover absence of relief, to equalize peak work periods or otherwise to balance the workload.

EMPLOYEE'S NAME (Print)	EMPLOYEE'S SIGNATURE	DATE

are currently using review panels. The osteopathic board and the speech-language board told us that they do not use review panels or other similar review processes. Specifically, the osteopathic board stated that it relies instead on the case reviews by its expert consultants. The physical therapy board stated that it is currently in the process of preparing to implement a quality control program and that its planned process will include board members reviewing closed cases to ensure timely resolutions and consistency in the process.

We recognize that the issues surrounding the review panels are not simple, but it is clear that the chiropractic board must take some action to remedy its noncompliance with its regulation. In determining what that action might be, we believe the board must consider its complaint review process more broadly. As we noted in previous sections of this chapter, the chiropractic board has not developed standard procedures or required management oversight of its complaint process. Therefore, by instituting a stronger system for reviewing and taking action on complaints, the board will be better able to determine what other processes it should add to complement its ability to promptly and appropriately respond to complaints about chiropractors.

Although we recognize that the issues surrounding the review panels are not simple, it is clear that the board must take some action to remedy its noncompliance with its regulation.

The Chiropractic Board's Recently Vacant Chiropractic Consultant Position Leaves a Gap in Its Available Technical Expertise

As noted in the Introduction, the chiropractic consultant position, under the supervision of the executive officer, provided chiropractic expertise to help staff review complaints against and evaluate the professional conduct of licensees who may have violated chiropractic laws and regulations. During our review, we found that the chiropractic board's enforcement process and its staff relied heavily on the chiropractic consultant to complete its reviews and make decisions on complaints and punishment when violations occurred. Because the chiropractic consultant position has been vacant since August 10, 2007, we asked the executive officer to provide his perspective on the impact to operations, especially to enforcement, licensing, and continuing education, of not having technical expertise on staff. The executive officer explained that because of the current budget situation, the chiropractic board is not planning to fill the vacant chiropractic consultant position. He also said that based on the chiropractic board's initial assessment of the enforcement program and the chiropractic consultant position in particular, it had concerns about the duties and use of the position and did not plan to fill the vacancy until a job analysis was conducted. At the same time, board members expressed concerns about filling the position before instituting a significant change in duties.

Instead, the chiropractic board is developing a group of expert consultants or witnesses to bridge the gap in technical expertise. The executive officer anticipates having the written procedures for handling expert consultants and witnesses in place by the end of March 2008 and to begin training staff by July 2008. He also stated that he anticipates that timeliness will not be an issue once internal enforcement staff are fully trained and able to quickly recognize when cases need referral to an expert. Further, the executive officer stated that enforcement staff will actively follow up with the consultants or experts to ensure that reports are provided promptly, and he believes that once the procedures are fully implemented, overall complaint handling times will decrease compared with prior years.

The chiropractic board is developing a group of expert consultants or witnesses to bridge the gap in technical expertise.

We also asked how the chiropractic board is addressing technical questions that it receives on its Web site, another function previously handled by the chiropractic consultant. The executive officer told us he was temporarily assigning scope-of-practice questions to board members to answer and confirmed that he reviews board members' responses to ensure that they are appropriate. He also stated that this is a temporary process that has been reduced and will be completely discontinued by the end of February 2008. Instead, the executive officer stated that the chiropractic board expects chiropractors, as licensed professionals, to have a clear understanding of the chiropractic scope of practice. Also, consistent with other boards within the Department of Consumer Affairs (Consumer Affairs), the chiropractic board can (1) determine if there is case law related to the question and if there is, provide the answer; (2) determine if there are attorney general opinions related to the question and if there are, provide the answer; (3) determine if there is only one reasonable interpretation of the law and if there is, provide the answer; or (4) if none of these apply, direct the individual to the relevant sections of law and recommend that if the individual still has questions, he or she should consider consulting a private attorney and the chiropractic board will review the opinion as long as it is provided in writing.

The executive officer also told us that licensing staff rarely have questions that need answers from a chiropractor, that the course approval process for continuing education is currently being reviewed to improve effectiveness, and that he anticipates the review and approval process of continuing education courses will be revamped. Finally, he stated that the chiropractic board is looking to incorporate a new structure to address gaps that may or may not include the hiring of a chiropractic consultant.

Although we acknowledge the concerns that the executive officer and board members have expressed about the chiropractic consultant position and the way that it was relied on and used in

We encourage the chiropractic board to consider having an expert on staff to ensure that it has invaluable expertise that is readily available to staff rather than having to rely on referrals to outside experts.

the past, we encourage the chiropractic board to consider having an expert on staff. The chiropractic board can establish processes to limit the autonomy of the position while still gaining invaluable expertise that is readily available to staff rather than having to rely on referrals to outside experts. For example, the chiropractic consultant could be used much like legal counsel to provide opinions to the executive officer, who would remain the final decision maker.

The Chiropractic Board Did Not Adequately Control the Use of Expert Witnesses

Chiropractic board policies and procedures for assigning a complaint case to an expert require the chiropractic consultant to conduct a telephone interview to assess an expert's experience and expertise with the relevant procedure or treatment. Performing such an interview before assigning a specific case assists the chiropractic board in ensuring that the expert is qualified and has no conflicts or disqualifying criteria such as personal or financial conflicts of interest, complaint history, or insufficient years of practice.

Our review of five complaints referred to experts revealed no evidence in the files demonstrating that staff performed telephone interviews before assigning the cases to experts. Board procedures do not require staff to document such efforts. In addition, the chiropractic board told us that it does not enter into contracts with experts for services. Such contracts would include standard language that informs contracting parties about their responsibilities regarding conflicts of interest. Further, the chiropractic board does not require staff to obtain documentation from experts attesting that they are free of conflicts of interest. Therefore, we could not confirm whether the staff appropriately assigned the cases we reviewed to qualified experts who are free of conflicts of interest.

Experts did not always complete their reviews within 30 days as expected. According to the chiropractic board's expert procedures, it expects an expert to finish reviewing the assigned case and file a written report within 30 days of assignment. The expert in only one of the four sample cases we examined completed the review and provided a written report within 30 days.[11] In two other cases, the experts submitted their reports within 45 days. In the fourth, the expert took more than 200 days to provide a report. Staff told us they perform no follow-up procedures, thus allowing unnecessary delays

[11] In another case, the expert review was already in progress on other related complaints when the board referred it; thus, we did not calculate the total days to receive the expert report.

BOARD OF CHIROPRACTIC EXAMINERS

OUT-OF-STATE TRAVEL REQUEST – FY 2009/10

Federation of Chiropractic Licensing Boards, Annual Conference.
Baltimore Marriott Inner Harbor at Camden Yards, Phone: 410-962-0202
Baltimore, Maryland, April 28, 2010 – May 2, 2010 **Trip #1**

ESTIMATED COST	
Registration Fee: 4 attendees @ $450.00 each	$ 1800.00
Hotel: $199.00 per night + $29.85 tax per night x 4 attendees x 5 nights	$ 4577.00
Food and incidentals: 4 days x $40.00 x 4 attendees	$ 640.00
Ground Transportation estimated cost:	$ 160.00
Estimated round trip airfare for 4 attendees $807.00 round trip – flexible fare	$ 3228.00
Total Estimated Cost:	**$ 10,405.00**

Justification for above FCLB trip:
The Federation of Chiropractic Licensing Boards (FCLB) is a national consortium of chiropractic licensing boards that works to facilitate sharing information among the states and Canadian provinces, to ensure accurate and timely reporting of disciplined licensees and set standards and procedures which will enhance chiropractic regulation on a national level. Because California licenses approximately 21-25% of the nation's chiropractors (including Canadian provinces), it is viewed as a leader in innovative and progressive advancements of the profession. Several years ago, the Board decided to increase its participation in FCLB affairs in order to facilitate more modern management of the organization and its meetings. This Board's involvement and participation in FCLB activities is important to the future of the organization, and also the future of the chiropractic profession nationwide.

The Council on Licensure, Enforcement and Regulation (CLEAR) conference.
Sheraton Denver Hotel, Phone: 800-444-2326
Denver, Colorado - September 10-12, 2009 **Trip # 2**

ESTIMATED COST	
Hotel: $145.00 + $21.75 tax per night x 3 attendees x 3 nights	$ 1500.75
Food and incidentals: 3 days x $40.00 x 3 attendees	$ 360.00
Ground Transportation estimated cost	$ 120.00
Conference registration: 3 x $500.00	$ 1500.00
Estimated round trip airfare for 3 attendees $549.80 round trip - flexible fare	$ 1649.40
Total Estimated Cost:	**$ 5130.15**

Justification for above CLEAR conference:
The Council on Licensure, Enforcement and Regulation (CLEAR) conference is the premier international resource for professional regulation stakeholders. Through its conferences, publications, training, inquiry and other services, CLEAR helps its members

carry out their shared mission of consumer protection. CLEAR has defined its own educator role as proactively identifying critical issues; providing a dynamic, interactive forum for exploration of these issues and collecting and disseminating relevant information on them. There are three core areas of substantive inquiry that CLEAR supports through its annual conference and other venues: professional discipline; credentialing/examination issues; and policy and administration.

Palmer College of Chiropractic, Davenport, IA **Trip # 3**

ESTIMATED COST (2007)	
Hotel: $113.00 + 16.95 taxes per night x 4 attendees x 2 nights	$ 1039.60
Food and incidentals: 2 days x $40.00 x 4 attendees	$ 320.00
Ground Transportation estimated cost	$ 100.00
Estimated round trip airfare flex fare is $648.00 x 4 attendees	$ 2592.00
Total Estimated Cost:	**$ 4051.60**

Texas College of Chiropractic, Pasadena, Texas **Trip # 4**

ESTIMATED COST (2007)	
Hotel: $113.00 + 16.95 taxes per night x 4 attendees x 2 nights	$ 1039.60
Food and incidentals: 2 days x $40.00 x 4 attendees	$ 320.00
Ground Transportation estimated cost	$ 100.00
Estimated round trip airfare flex fare is $684.50 for 4 attendees	$ 2738.00
Total Estimated Cost:	**$ 4197.60**

Justification for above Chiropractic College Visits:
The Board has the authority to approve chiropractic colleges for students to attend prior to licensure with the State of California. The Board has made it a priority to visit and inspect those chiropractic colleges that have been approved or are pending Board approval. It is important to maintain contact with approved chiropractic schools to ensure that they are meeting the requirements of Board-approval and that they are meeting the requirements of the Chiropractic Initiative Act when instructing students. It is the Board's goal to visit 2-3 colleges per year on a rotational basis to maintain a strong presence with the chiropractic colleges.

STATE OF CALIFORNIA

BOARD OF CHIROPRACTIC EXAMINERS | ARNOLD SCHWARZENEGGER, GOVERNOR

MEMORANDUM

Date: March 16, 2009

To: Brian J. Stiger,
Executive Officer

From: Genie Mitsuhara
Continuing Education Analyst

Subject: **Ratification of Formerly Approved Continuing Education Providers**

This confirms that the Board of Chiropractic Examiners did not approve any Continuing Education Providers during this reporting period

If you have any questions or concerns, please contact me at your earliest opportunity.

STATE OF CALIFORNIA

BOARD OF CHIROPRACTIC EXAMINERS | ARNOLD SCHWARZENEGGER, GOVERNOR

MEMORANDUM

Date: March 5, 2009

To: **Board Members**

From: Brian J. Stiger
Executive Officer

Subject: **Ratification of Formerly Approved Doctors of Chiropractic for Licensure**

This is to request that the Board ratify the attached list of individuals as Doctors of Chiropractic at the March 26, 2009, public meeting.

Between December 23, 2008 and February 28, 2009, staff reviewed and confirmed that the applicants met all statutory and regulatory requirements.

If you have any questions or concerns, please contact me at your earliest opportunity.

Approval By Ratification of Formerly Approved License Applications
December 23, 2008 – February 28, 2009

Name (First, Middle, Last)			Date Issued	DC#
Gerald		Nastasia Jr.	1/2/2009	**31098**
Michael	Lee	Kemper	1/9/2009	**31099**
Anish	Jai	Chandra	1/9/2009	**31100**
John	Jason	Cherry	1/9/2009	**31101**
Sara		Aramipour	1/9/2009	**31102**
Matthew	Walter	Hassey	1/13/2009	**31103**
Natalie	Marie	King	1/13/2009	**31104**
Daniel	Joseph	Jacobazzi	1/13/2009	**31105**
Elizabeth	Starr	Molina	1/13/2009	**31106**
Jonathan	Bao	Huynh	1/20/2009	**31107**
Mike	Seth	Kuoppamaki	1/20/2009	**31108**
Kristine	Kay	Brew	1/20/2009	**31109**
Katharine	Elizabeth	Randall	1/20/2009	**31110**
David	C.	Savage	2/24/2009	**31111**
Allison	Courtney	Spencer	1/20/2009	**31112**
Steve		Thao	1/20/2009	**31113**
Jeffrey	Martin	Thompson	1/20/2009	**31114**
Lee	Russell	Towasser	1/20/2009	**31115**
Shannon	Gerald	Watson	1/20/2009	**31116**
Long	Lonnie	Yang	1/20/2009	**31117**
Malinda	My Hong	Nguyen	1/20/2009	**31118**
Arash		Pershen	1/20/2009	**31119**
Susan	Marie	Anderson	2/2/2009	**31120**
Amber	Nicole	Kingsley	2/2/2009	**31121**
Brenda		Basken	2/2/2009	**31122**
Corey	Scott	Erlitz	2/2/2009	**31123**
Geoffrey	Anson	Allen	2/2/2009	**31124**
Patrick		Khaziran	2/2/2009	**31125**
Hans	Christian	Delfo	2/2/2009	**31126**
Tracy	Lynn	Foley	2/2/2009	**31127**
Mohammad	Adam	Moradi	2/2/2009	**31128**
Carrol	Yoonjung	Baek	2/10/2009	**31129**
Daniel	Adrian	Maldonado	2/10/2009	**31130**
Kyle	Bruce	Bills	2/10/2009	**31131**
Steven	Lawrence	Black	2/10/2009	**31132**
Jason	Dean	Kennedy	2/10/2009	**31133**

Marcie	Shane	Morton	2/17/2009	**31134**
Kristina	Marie	Blum	2/17/2009	**31135**
Kacie	Karmen	Flegal	2/17/2009	**31136**
Sebastian	Andrew	Gonzales III	2/17/2009	**31137**
Paul	Crispin	Barkmeier	2/17/2009	**31138**
Damien	Johann	Burgess	2/19/2009	**31139**
Clorinda	Yuen Mon	Lau	2/19/2009	**31140**
Derek	Phillip	Gibbons	2/19/2009	**31141**
Jack	Thomas	Li	2/19/2009	**31142**
Michael	Thomas	Buckle	2/19/2009	**31143**
Cassandra	Marie	Herbst	2/19/2009	**31144**
Roslyn		Migdale	2/19/2009	**31145**
Charlotte	Elizabeth	Campbell	2/19/2009	**31146**
Daniel	Eric	Glimpse	2/19/2009	**31147**
Jason	Matthew	Higgins	2/19/2009	**31148**
Christopher	William	George	2/19/2009	**31149**
Evan	John	Mountford	2/19/2009	**31150**
Amanda	Elizabeth	Apesos	2/19/2009	**31151**
Ian	Sheene	Davis-Tremayne	2/19/2009	**31152**
Matthew	Howard	Cobb	2/19/2009	**31153**
Jay	Chae-Hun	Lee	2/19/2009	**31154**
Sang Woen	Arthur	Hong	2/19/2009	**31155**
Jason	William	Bergerhouse	2/23/2009	**31156**
Katherine	Elizabeth	Lyn	2/23/2009	**31157**
Joshua	Jay	Knowles	2/23/2009	**31158**
Pawen	Singh	Dhokal	2/23/2009	**31159**
Carley	Plantrich	Fardell	2/23/2009	**31160**
Jonathan	Zhiqiang	Guan	2/23/2009	**31161**
Sarah	Rebekah	Martinez	2/23/2009	**31162**
Dorea	Leigh	Wilder	2/23/2009	**31163**
Brian	George	Najor	2/24/2009	**31164**
Maryam		Noorivaziri	2/24/2009	**31165**
Shannon	Marie	Ozier	2/24/2009	**31166**
Il	Hwan	Park	2/24/2009	**31167**
Amy	Joy	Pietrowski	2/24/2009	**31168**
Adam	Dennis	Poole	2/24/2009	**31169**
Justine	Jee-Eun	Rhee	2/24/2009	**31170**
David	Jerome	Saber	2/24/2009	**31171**
Jacob	George	Sahourieh	2/24/2009	**31172**
Joseph	Dayao	Sapiandante	2/24/2009	**31173**
Stephen	Brent	Waller	2/24/2009	**31174**
Seung	Wook	Yun	2/24/2009	**31175**
Mandi	Lynne	Miedema	2/26/2009	**31176**

Bonnie	Lianne	Fischer	2/26/2009	**31177**
Leslie	Lee	Berneske	2/26/2009	**31178**
Erica	Ann	Martin	2/26/2009	**31179**
Amy	Michelle	Hernandez	2/26/2009	**31180**
Megan	Shay	Mordecai	2/26/2009	**31181**
Amie	Beth	Gregory	2/26/2009	**31182**
Erica	Jean	Blankenbehler	2/26/2009	**31183**
Dayna	Joelle	Blum	2/26/2009	**31184**

STATE OF CALIFORNIA

BOARD OF CHIROPRACTIC EXAMINERS | ARNOLD SCHWARZENEGGER, GOVERNOR

MEMORANDUM

Date: March 13, 2009

To: **Board Members**

From: Brian J. Stiger
Executive Officer

Subject: **Ratification of Formerly Denied License Applications**

The Board of Chiropractic Examiners (Board) denies licensure to applicants who do not meet all statutory and regulatory requirements for a chiropractic license in California. An applicant has 60-days after the denial is issued to appeal the decision. If the applicant does not submit an appeal to the Board, the denial is upheld.

During January 1, 2009, and February 28, 2009, staff reviewed and confirmed that three (3) applicants did not meet all requirements for licensure. Of these, one (1) has appealed the denial of their license application. The Board is working with the Office of the Attorney General on this appeal. The remaining applicants are still within their 60-day period to appeal our decision.

The attached is a list of individuals who were denied licensure as Doctors of Chiropractic and did not request a hearing. This is to recommend that the Board ratify the denials at the March 26, 2009, public meeting.

If you have any questions or concerns, please contact me at your earliest opportunity.

Ratification of Formerly Denied License Applications
Applicants Did Not Submit an Appeal

January 1, 2009 – February 28, 2009

Name (First, Middle, Last) **Date Denied**
Reason for Denial

Donatelli, Anthony **11/26/2008**

Criminal Convictions:

- Conspiracy to Possess with Intent to Distribute Anabolic Steriods - **Felony**
- Facilitating Smuggling of Schedule III Controlled Substances; aiding and abetting– **Felony**

Disciplinary Actions in other States:

- **State of Virginia**: license **indefinitely suspended** for violating terms of probation
- **State of Rhode Island**: license **revoked** for illegal and unprofessional conduct

STATE OF CALIFORNIA

BOARD OF CHIROPRACTIC EXAMINERS | ARNOLD SCHWARZENEGGER, GOVERNOR

MEMORANDUM

Date: March 13, 2009

To: **Board Members**

From: Brian J. Stiger
Executive Officer

Subject: Recommendation to Waive Two Year Requirement on Restoration of a Cancelled License – Chiropractic Initiative Act, Section 10(c)

This is to recommend that the Board waive the two year restoration requirement of a cancelled license for the individuals named on the attached list at the March 26, 2009, public meeting.

Staff reviewed and confirmed that the applicants met all other regulatory requirements for restoration including sufficient continuing education hours.

If you have any questions or concerns, please contact me at your earliest opportunity.

Recommendation to Waive Two Year Requirement on Restoration of a Cancelled License

Name (Last, First MI)	License No.	Cancellation Date
Gross, Dale Martin	16398	06/30/2007
Herschorn, Jack	11929	10/31/2008
Kim, Alex Stevens	28968	03/30/2008
Origel, Wilmer Dorado	16790	05/31/2008
Weed, Douglas Lewis	13418	10/31/2008
Yang, Roger	25633	06/30/2007

Joint Committee on Boards, Commissions & Consumer Protection
Sunset Review Report
September 2005

- The Board is carefully reviewing the current fee structure for several areas where fees are collected. The Board currently does not have the regulatory authority to collect the corporation annual report filing fee, duplicate renewal receipt fee, satellite renewal fee, and license certification fee, all fees it has historically charged. In order to realign the fee structure the Board is researching what the appropriate fee amount should be for the services rendered. Presently, the cost to prepare the document is more than the amount the Board charges.

- To ensure the Board is reimbursed for providing related services, the Board staff is proposing a new fee structure by securing proper authority to charge such fees and establishing them at the following levels:

Fee Schedule	Current Fee	Proposed Fee
Application Fee	$100	*$ 100
Initial License Fee	$100	*$ 100
Renewal Fee	$150	*$ 100
Duplicate Receipt/Renewal License***	$ 5	$ 25
Inactive License Renewal Fee	$150	$ 70
Forfeiture Fee (late renewal fee)	$150	*$ 100
College Approval Application Fee***	0	$1,500
Continuing Education Course Fee	$ 50	**$ 30
Continuing Education Provider Fee***	0	$ 350
Continuing Education Provider Renewal Fee***	0	$ 200
Corporation Registration Application Fee	$100	$ 250
Corporation Special Report Filing Fee	$ 5	$ 40
Corporation Annual Renewal Fee***	$ 10	$ 150
License Certification/Out-of-State Verif.***	$ 10	$ 50
Reciprocal License Application Fee	$ 25	$ 125
Referral Service Application Fee	$ 25	$ 150
Replacement License Fee	$ 25	$ 40
Satellite Certificate Application Fee	$ 5	$ 50
Satellite Renewal Fee***	$ 5	$ 50

*Authority for fee amount is in the Act.
**Per each hour of course content requested.
***These fees will need to be established in the proposed fee regulation.

A revised fee structure is necessary to bring the charges more in-line with the services. It is anticipated that it will ultimately increase the Board's revenues. To offset the increased fees, a reduction in the annual renewal fee, forfeiture fee, and inactive license fee is proposed. Prior to any fee restructure the Board will consult with Department of General Services, which prepares the Board's fund condition to determine the impact of the revised fee schedule on the Board's overall budget.

STATE OF CALIFORNIA ARNOLD SCHWARZENEGGER, Governor

Board of Chiropractic Examiners
2525 Natomas Park Drive, Suite 260
Sacramento, California 95833-2931
Telephone (916) 263-5355 FAX (916) 263-5369
CA Relay Service TT/TDD (800) 735-2929
Consumer Complaint Hotline (866) 543-1311
www.chiro.ca.gov

Proposed Legislation to Increase License Fees

January 8, 2009

The amount of fees prescribed by this article is fixed by the following schedule:

(a) The fee for filing an application for the doctor of chiropractic examination shall be set by the board at a minimum of one hundred twenty five dollars ($125) not to exceed three hundred fifty dollars ($350).

(b) The initial license fee for a doctor of chiropractic shall be set by the board at a minimum of one hundred twenty five dollars ($125) not to exceed two hundred fifty dollars ($250).

(c) The annual renewal fee for a doctor of chiropractic shall be set by the board at a minimum of two hundred dollars ($200) not to exceed three hundred fifty dollars ($350).

(d) The annual renewal fee for an inactive active doctor of chiropractic license shall be set at the same amount as the annual renewal fee of an active doctor of chiropractic license.

(e) The fee for filing an application to return an inactive license to active status shall be set by the board at a minimum of seventy dollars ($70) not exceed one hundred fifty dollars ($150).

(f) The fee for filing an application to restore a cancelled license to an active license shall be set at twice the annual renewal fee for a doctor of chiropractic.

(g) The fee for filing an application for approval of a chiropractic school or college shall be set by the board at a minimum of one thousand five hundred dollars ($1,500). The chiropractic school or college shall also pay for the actual costs of an onsite inspection conducted by the board, including, but not limited to, the travel, food, and lodging expenses incurred by an inspection team sent by the board.

(h) The annual renewal fee for a chiropractic school or college shall be set by the board at a minimum of two hundred fifty dollars ($250) not to exceed five hundred dollars ($500).

(i) The fee for filing an application to register a chiropractic corporation shall be set by the board at a minimum of two hundred fifty dollars ($250) not to exceed five hundred dollars ($500).

(j) The annual renewal fee for a chiropractic corporation shall be set by the board at a minimum of one hundred fifty dollars ($150) not to exceed four hundred dollars ($400).

(k) The fee for filing an application for a satellite certificate shall be set by the board at a minimum of seventy five dollars ($75) not to exceed one hundred fifty dollars ($150).

(l) The annual renewal fee for a satellite certificate shall be set by the board at a minimum of fifty dollars ($50) not to exceed one hundred fifty dollars ($150).

(m) The fee for filing an application for a reciprocal license shall be set by the board at a minimum one hundred twenty five dollars ($125) not to exceed three hundred fifty dollars ($350).

(n) The fee for filing an application for a continuing education provider shall be set by the board at a minimum of three hundred fifty dollars ($350) not to exceed five hundred dollars ($500).

(o) The annual renewal fee for a continuing education provider shall be set by the board at a minimum of two hundred dollars ($200) not to exceed four hundred dollars ($400).

(p) The fee for filing an application to approve a continuing education course shall be set by the board at a minimum of seventy five dollars ($75) not to exceed one hundred fifty dollars ($150) for each course.

(q) The fee for filing an application for a referral service application shall be set by the board at a minimum of one hundred fifty dollars ($150) not to exceed three hundred fifty dollars ($350).

(r) The annual renewal fee for a referral service shall be set by the board at a minimum of one hundred dollars ($100) not to exceed three hundred dollars ($300).

(s) The forfeiture fee or delinquency fee for subsections (c), (h), (j), (l), and (o) of this section shall be set at twice the annual renewal fee for that subsection.

(t) Any charge made for duplication or other services shall be set at the cost of rendering the services.

STATE OF CALIFORNIA ARNOLD SCHWARZENEGGER, Governor

Board of Chiropractic Examiners
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Consumer Complaint Hotline (866) 543-1311
www.chiro.ca.gov

Bill Number: AB 361
Introduced: February 23, 2009

Author: Bonnie Lowenthal
Vote: Majority

Bill Summary:

This bill prohibits an insurance company that provides workers' compensation coverage from rescinding an authorization for medical services after the services are rendered.

Purpose of the Bill:

According to the author, some insurance companies will grant authorization for a course of treatment and then deny reimbursement when the doctor sends in the bill after the authorized care was provided. This problem was remedied within group health settings through legislation, but the problem still exits within the workers' compensation system.

Existing Law:

Establishes a workers' compensation system to compensate an employee for injuries sustained during the course of employment; requires employers to establish a medical treatment utilization review process; and requires an employer or insurer to establish or modify a medical provider network for the provision of medical treatment to injured employees.

Specifically, this bill would:

- Require insurance companies to pay for the medical services they authorize providers under workers' compensation to perform, even if insurance companies do so in error.
- Extend the AB 1324 (De La Torre, 2007) protections to workers' compensation claims by adding the same language to section 4610.3 to the Labor Code.

Fiscal Impact:

None

Staff Recommendation:

The BCE staff recommends a support position.

ASSEMBLY BILL No. 361

Introduced by Assembly Member Bonnie Lowenthal
(Coauthors: Assembly Members Ammiano, Coto, and Torlakson)

February 23, 2009

An act to add Section 4610.3 to the Labor Code, relating to workers' compensation.

LEGISLATIVE COUNSEL'S DIGEST

AB 361, as introduced, Bonnie Lowenthal. Workers' compensation: treatment authorization.

Existing law establishes a workers' compensation system, administered by the Administrative Director of the Division of Workers' Compensation, to compensate an employee for injuries sustained in the course of his or her employment. Existing law requires every employer to establish a medical treatment utilization review process, in compliance with specified requirements, either directly or through its insurer or an entity with which the employer or insurer contracts for these services.

Existing law authorizes an employer or insurer to establish or modify a medical provider network for the provision of medical treatment to injured employees, and to submit a medical provider network plan to the administrative director for approval. Existing law permits employers to enter into contracts for the provision of medical services to injured employees with a health care organization that has been certified by the administrative director for this purpose.

This bill provides that, regardless of whether an employer has established a medical provider network or entered into a contract with a health care organization, an employer that authorizes medical treatment shall not rescind or modify that authorization for any reason, including,

but not limited to, the employer's subsequent determination that the physician who treated the employee was not eligible to treat that injured employee. This bill provides that its provisions shall not be construed to expand or alter the benefits available under, or the terms and conditions of, any contract.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4610.3 is added to the Labor Code, to read:

4610.3. (a) Regardless of whether an employer has established a medical provider network pursuant to Section 4616 or entered into a contract with a health care organization pursuant to Section 4600.5, an employer that authorizes medical treatment shall not rescind or modify that authorization for any reason, including, but not limited to, the employer's subsequent determination that the physician who treated the employee was not eligible to treat that injured employee.

(b) This section shall not be construed to expand or alter the benefits available under, or the terms and conditions of, any contract.

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Bill Number: SB 389
Introduced: February 26, 2009

Author: Negrete McLeod
Vote: Majority

Bill Summary:

This bill would provide the Board of Chiropractic Examiners (BCE) the authority to require applicants and licensees who have not previously submitted fingerprints, or a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information. This bill would also require a licensee to notify the BCE of any felony or misdemeanor convictions since their last renewal.

Purpose of the Bill:

This bill is intended to increase consumer protection and to clarify the BCE's authority to require applicants/licensees to submit fingerprints.

Existing Law:

Provides various professions and vocations within the Department of Consumer Affairs to suspend or revoke a license on various grounds; and requires applicants of certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record verification.

Specifically, this bill would:

- Make fingerprinting requirements applicable to BCE;
- Require applicants for licensure to submit fingerprints for state and federal back ground checks;
- Effective January 1, 2011, will require licensees who have not previously submitted fingerprints, or a record of fingerprints no longer exists, to submit fingerprints for state and federal back ground checks;
- Require a licensee to notify the BCE of any convictions, as defined, of a felony or misdemeanor since their last renewal;
- A licensee that fails to comply with this statute is subject to disciplinary action for making a false certification.

Fiscal Impact:

The BCE will experience an increase in workload associated with the review and processing of licensees that a record of fingerprinting no longer exists. However, the BCE staff believes this would not significantly increase workload and will be able to be absorbed with existing staff.

Staff Recommendation:

The BCE staff recommends a support position.

SENATE BILL No. 389

Introduced by Senator Negrete McLeod

February 26, 2009

An act to amend Section 144 of, and to add Sections 144.5 and 144.6 to, the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 389, as introduced, Negrete McLeod. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law authorizes a board to suspend or revoke a license on various grounds, including, but not limited to, conviction of a crime, if the crime is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued. Existing law requires applicants to certain boards to provide a full set of fingerprints for the purpose of conducting criminal history record checks.

This bill would make that fingerprinting requirement applicable to the Dental Board of California, the Dental Hygiene Committee of California, the Professional Fiduciary Bureau, the Osteopathic Medical Board of California, the California Board of Podiatric Medicine, and the State Board of Chiropractic Examiners. The bill would require applicants for a license and, commencing January 1, 2011, licensees who have not previously submitted fingerprints, or for whom a record of the submission of fingerprints no longer exists, to successfully complete a state and federal level criminal offender record information search, as specified. The bill would require licensees to certify compliance with that requirement, as specified, and would subject a licensee to disciplinary action for making a false certification. The bill

would also require a licensee to, as a condition of renewal of the license, notify the board on the license renewal form if he or she has been convicted, as defined, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 144 of the Business and Professions Code is amended to read:

144. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) shall require an applicant *for a license* to furnish to the agency a full set of fingerprints for purposes of conducting criminal history record checks *and shall require the applicant to successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice as provided in subdivision (c) or as otherwise provided in this code.* ~~Any agency designated in subdivision (b) may obtain and receive, at its discretion, criminal history information from the Department of Justice and the United States Federal Bureau of Investigation.~~

(b) Subdivision (a) applies to the following:

(1) California Board of Accountancy.

(2) State Athletic Commission.

(3) Board of Behavioral Sciences.

(4) Court Reporters Board of California.

(5) State Board of Guide Dogs for the Blind.

(6) California State Board of Pharmacy.

(7) Board of Registered Nursing.

(8) Veterinary Medical Board.

(9) Registered Veterinary Technician Committee.

(10) Board of Vocational Nursing and Psychiatric Technicians.

(11) Respiratory Care Board of California.

(12) Hearing Aid Dispensers ~~Advisory Commission~~ *Bureau*.

(13) Physical Therapy Board of California.

(14) Physician Assistant Committee of the Medical Board of California.

(15) Speech-Language Pathology and Audiology Board.

(16) Medical Board of California.
(17) State Board of Optometry.
(18) Acupuncture Board.
(19) Cemetery and Funeral Bureau.
(20) Bureau of Security and Investigative Services.
(21) Division of Investigation.
(22) Board of Psychology.
(23) ~~The~~ California Board of Occupational Therapy.
(24) Structural Pest Control Board.
(25) Contractors' State License Board.
(26) Bureau of Naturopathic Medicine.
(27) Dental Board of California.
(28) Dental Hygiene Committee of California.
(27) Professional Fiduciaries Bureau.
(28) California Board of Podiatric Medicine.
(29) Osteopathic Medical Board of California.
(30) State Board of Chiropractic Examiners.

~~(c) The provisions of paragraph (24) of subdivision (b) shall become operative on July 1, 2004. The provisions of paragraph (25) of subdivision (b) shall become operative on the date on which sufficient funds are available for the Contractors' State License Board and the Department of Justice to conduct a criminal history record check pursuant to this section or on July 1, 2005, whichever occurs first.~~

(c) Except as otherwise provided in this code, each agency listed in subdivision (b) shall direct applicants for a license to submit to the Department of Justice fingerprint images and related information required by the Department of Justice for the purpose of obtaining information as to the existence and content of a state or federal criminal record. The Department of Justice shall forward the fingerprint images and related information received to the Federal Bureau of Investigation and request federal criminal history information. The Department of Justice shall compile and disseminate state and federal responses to the agency pursuant to subdivision (p) of Section 11105 of the Penal Code. The agency shall request from the Department of Justice subsequent arrest notification service, pursuant to Section 11105.2 of the Penal Code, for each person who submitted information pursuant to this subdivision. The Department of Justice shall charge a fee sufficient to cover the cost of processing the request described in this section.

SEC. 2. Section 144.5 is added to the Business and Professions Code, to read:

144.5. (a) Notwithstanding any other provision of law, an agency designated in subdivision (b) of Section 144 shall require a licencee who has not previously submitted fingerprints or for whom a record of the submission of fingerprints no longer exists to, as a condition of license renewal, successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice as provided in subdivision (d).

(b) (1) A licensee described in subdivision (a) shall, as a condition of license renewal, certify on the renewal application that he or she has successfully completed a state and federal level criminal offender record information search pursuant to subdivision (d).

(2) The licensee shall retain for at least three years, as evidence of the certification made pursuant to paragraph (1), either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those licensees who did not use an electronic fingerprinting system, a receipt evidencing that the licensee's fingerprints were taken.

(c) Failure to provide the certification required by subdivision (b) renders an application for renewal incomplete. An agency shall not renew the license until a complete application is submitted.

(d) Each agency listed in subdivision (b) of Section 144 shall direct licensees described in subdivision (a) to submit to the Department of Justice fingerprint images and related information required by the Department of Justice for the purpose of obtaining information as to the existence and content of a state or federal criminal record. The Department of Justice shall forward the fingerprint images and related information received to the Federal Bureau of Investigation and request federal criminal history information. The Department of Justice shall compile and disseminate state and federal responses to the agency pursuant to subdivision (p) of Section 11105 of the Penal Code. The agency shall request from the Department of Justice subsequent arrest notification service, pursuant to Section 11105.2 of the Penal Code, for each person who submitted information pursuant to this subdivision. The Department of Justice shall charge a fee sufficient to cover the cost of processing the request described in this section.

(e) An agency may waive the requirements of this section if the license is inactive or retired, or if the licensee is actively serving in the military. The agency may not activate an inactive license or return a retired license to full licensure status for a licensee described in subdivision (a) until the licensee has successfully completed a state and federal level criminal offender record information search pursuant to subdivision (d).

(f) With respect to licensees that are business entities, each agency listed in subdivision (b) of Section 144 shall, by regulation, determine which owners, officers, directors, shareholders, members, agents, employees, or other natural persons who are representatives of the business entity are required to submit fingerprint images to the Department of Justice and disclose the information on its renewal forms, as required by this section.

(g) A licensee who falsely certifies completion of a state and federal level criminal record information search under subdivision (b) may be subject to disciplinary action by his or her licensing agency.

(h) This section shall become operative on January 1, 2011.

SEC. 3. Section 144.6 is added to the Business and Professions Code, to read:

144.6. (a) An agency described in subdivision (b) of Section 144 shall require a licensee, as a condition of license renewal, to notify the board on the license renewal form if he or she has been convicted, as defined in Section 490, of a felony or misdemeanor since his or her last renewal, or if this is the licensee's first renewal, since the initial license was issued.

(b) The reporting requirement imposed under this section shall apply in addition to any other reporting requirement imposed under this code.

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Bill Number: SB 762 **Author: Aanestad**
Introduced: February 27, 2009 **Vote: Majority**

Bill Summary:

This bill would make it unlawful for a city or county to prohibit a healing arts licensee from engaging in any act or procedure that falls within the professionally recognized scope of practice of that licensee.

Purpose of the Bill:

This bill ensures that local city and county governments do not interfere with the appropriate practice of licensed healing arts professions that falls within the jurisdiction of the appropriate state licensing agency.

Existing Law:

It is unlawful for local city or county agency to restrict a person or business licensed by the Department of Consumer Affairs to engage in a particular business or profession.

Specifically, this bill would:

- Prohibit the city or county from prohibiting a healing arts licensed profession from engaging in any act or procedure that falls within the scope of practice of that license;
- Ensures that local city and county agencies may levy a business or license tax solely for revenue purposes, as appropriate.

Fiscal Impact:

None

Staff Recommendation:

The BCE staff recommends a support position.

SENATE BILL No. 762

Introduced by Senator Aanestad

February 27, 2009

An act to amend Section 460 of the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 762, as introduced, Aanestad. Professions and vocations: healing arts.

Existing law makes it unlawful for a city or county to prohibit a person, authorized by one of the agencies of the Department of Consumer Affairs to engage in a particular business, from engaging in that business, occupation, or profession or any portion thereof.

This bill would also make it unlawful for a city, county, or city and county to prohibit a healing arts licensee from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee, but would prohibit construing this provision to prohibit the enforcement of a local ordinance effective prior to January 1, 2010, as specified.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 460 of the Business and Professions Code is amended to read:

460. *(a)* No city or county shall prohibit a person *or group of persons*, authorized by one of the agencies in the Department of Consumer Affairs by a license, certificate, or other such means to engage in a particular business, from engaging in that business,

occupation, or profession or any portion thereof. ~~Nothing in this section shall prohibit any city or county or city and county from levying a business license tax solely for revenue purposes nor any city or county from levying a license tax solely for the purpose of covering the cost of regulation.~~

(b) No city, county, or city and county shall prohibit a healing arts professional licensed with the state under Division 2 (commencing with Section 500) from engaging in any act or performing any procedure that falls within the professionally recognized scope of practice of that licensee. This subdivision shall not be construed to prohibit the enforcement of a local ordinance effective prior to January 1, 2010, related to any act or procedure that falls within the professionally recognized scope of practice of a healing arts professional licensed under Division 2 (commencing with Section 500).

(c) Nothing in this section shall prohibit any city, county, or city and county from levying a business license tax solely for revenue purposes, nor any city or county from levying a license tax solely for the purpose of covering the cost of regulation.

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Board of Chiropractic Examiners (BCE)
Proposed Regulations - Status

Proposed Regulation	Purpose	Status
Letter of Admonishment	To authorize the BCE the ability to issue a letter of admonishment to licensees for failure to comply with any laws or regulations governing the practice of chiropractic. This provides the BCE with an informal method to address minor violations that do not rise to the level of citations or an accusation.	March 4, 2009: Office of Administrative Law (OAL) approves the proposed regulations April 3, 2009: Effective date of the regulatory action
Chiropractic Quality Review Panels (CQRP)	To repeal the requirements of CQRP's. As of today, this regulation has not been implemented. As currently written, this regulation is too expensive to implement, the panels created would be ineffective due to their limited scope of action, and the member's lack of knowledge of procedures could promote inconsistency in rulings.	March 3, 2009: OAL approves the proposed regulations April 2, 2009: Effective date of the regulatory action
Manipulation Under Anesthesia (MUA)	To establish a safe standard of care when a chiropractor is performing MUA.	February 24, 2009: Public hearing in Sacramento March 26, 2009: Board Members to review written and oral comments received during the 45-day comment period March 31, 2009: Projected filing of modified proposed language, if applicable April 10, 2009 – April 24, 2009: Projected 15-day written comment period

Continuing Education (CE)	To increase CE hours to be consistent with other healing arts Boards, determine subject matter of required courses, approve distance learning courses, and include the BCE's approval, denial, and appeal process in regulations.	March 24, 2009: Projected filing with OAL April 3, 2009 – May 18, 2009: Projected 45-day written comment period May 18, 2009: Projected public hearing in Sacramento
Petitions for Reinstatement	To extend the time frame that a licensee may petition the board for reinstatement of a license, modifications of probation, or early termination or probation.	March 24, 2009: Projected filing with OAL April 3, 2009 – May 18, 2009:Projected 45-day written comment period May 19, 2009: Projected public hearing in Sacramento
Chiropractic Specialties	To recognize Chiropractic Specialties.	March 31, 2009: Projected filing with OAL April 10, 2009 – May 25, 2009: Projected 45-day written comment period May 27, 2009: Projected public hearing in Sacramento
Fingerprinting of Applicants and Licensees	Authorizes the BCE to require previously fingerprinted licensees to provide electronic updated fingerprints.	April 14, 2009: Projected filing date with OAL April 24, 2009 - June 8, 2009: Projected 45-day written comment period June 10, 2009: Projected public hearing in Sacramento

Board of Chiropractic Examiners
Proposed Regulations
Title 16, Division 4, California Code of Regulations

§ 389. Letter of Admonishment.

(a) The Executive Officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with any provision of the Act, statute or regulations governing the practice of chiropractic.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the Act, statute or regulation violated and may contain an order of abatement.

(c) The letter of admonishment shall be served upon the licensee personally or by certified United States mail at the licensee's address of record with the board. If the licensee is served by certified United States mail, service shall be effective upon deposit in the United States mail.

(d) The letter of admonishment shall inform the licensee that within 30 days of the date of the letter the licensee may do either of the following:

(1) Submit a written request for an office conference to the Executive Officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the Executive Officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the Executive Officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference. Upon request and approval by the Executive Officer or his or her designee, the licensee may participate in the office conference by telephone.

(B) Prior to or at the office conference, the licensee may submit to the Executive Officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The Executive Officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the Executive Officer, or his or her designee, shall personally serve or send by certified United States mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(D) Within thirty days of service or mailing of the written decision, the licensee shall comply with the letter of admonishment and, if the letter of admonishment contains an order of abatement, the licensee shall submit documentation to the Executive Officer documenting compliance with the order.

(2) Comply with the letter of admonishment and, if the letter of admonishment contains an order of abatement, the licensee shall submit documentation to the Executive Officer documenting compliance with the order.

NOTE: Authority cited: Sections 1000-4(b) 1000-10, and 125.9 Business and Professions Code; and Chiropractic Initiative Act of California, Stats. 1923, p. 1xxxviii. Reference: Sections 1000-4(b) and 1000-10, Business and Professions Code; and Chiropractic Initiative Act of California, Stats. 1923, p. 1xxxviii.

HISTORY: 1. New section filed 9-25-2000; operative 10-25-2000 (Register 2000, No. 39).

Board of Chiropractic Examiners
Proposed Regulations
Title 16, Division 4, California Code of Regulations

§305. Procedure in Disciplinary Proceedings.

All proceedings relating to the refusal to grant, suspension or revocation of a license to practice chiropractic, or for the reissuance or reinstatement of a license which has been suspended or revoked, or for the disciplining of licensees in any manner ~~other than by a Chiropractic Quality Review Panel,~~ shall be conducted in accordance with the provisions of Section 11500 et seq. of Chapter 5 of Part 1 of Division 3 of Title 2 of the Government Code.

NOTE: Authority cited: Sections 1000-4(b), 1000-4(e) and 1000-10(b), Business and Professions Code (Chiropractic Initiative Act). Reference: Section 1000-4(h), Business and Professions Code.

~~§306.1. Chiropractic Quality Review Panel (CQRP).~~

~~The board shall establish a Chiropractic Quality Review Panel (CQRP) by county throughout California to hear cases referred by the board's Executive Officer.~~

~~(a) The authority and duties of CQRP's are:~~

~~(1) To review chiropractic care provided by California licensees.~~

~~(2) To act on all matters assigned to it by the board's Executive Officer.~~

~~(3) To inspect all chiropractic records where reasonable cause exists to initiate a quality review.~~

~~(b) The composition and purpose of CQRP's are as follows:~~

~~(1) Each panel shall be composed of three licensees appointed by the board.~~

~~(2) Each panel member shall have at least 5 years experience practicing chiropractic in California.~~

~~(3) Each panel member shall have no disciplinary action against their license.~~

~~(4) The purpose of the CQRP is to review specific complaints and where appropriate to provide recommendations of continuing education and to strengthen aspects of the licensee's chiropractic practice.~~

~~(A) The "continuing education" recommendations are limited to specific continuing education seminars required by licensees.~~

~~(B) "Recommendations to strengthen aspects of a licensee's practice" will be a panel recommendation consistent with chiropractic standards of care in California.~~

~~(c) CQRP Hearing Procedures are as follows:~~

~~(1) A closed panel hearing shall be conducted with a court reporter.~~

~~(2) Any licensee required to appear before a panel will be notified by certified mail with a summary of the specific complaint together with supporting documents at least 30 days prior to the scheduled panel hearing.~~

~~(3) When requested by the panel, licensees shall present to the panel all patient treatment records relevant to the specific complaint as required by California Code of Regulations, Title 16, Section 318.~~

~~(4) The failure to present all requested patient records authorizes the panel to presume that the information in the records is adverse to the licensee.~~

~~(5) The licensee may bring in any witnesses and documents to assist in responding to the complaint.~~

~~(6) The licensee may have counsel present during the panel hearing.~~

~~(7) The licensee will be given an adequate opportunity to respond to any questions by the panel.~~

~~(8) A postponement of the scheduled panel hearing may be granted by the board's Executive Officer upon a showing of good cause made at least 10 days prior to the scheduled hearing.~~

~~(9) The failure of a licensee to appear, without good cause, constitutes grounds for a recommendation to the Executive Officer for filing of a disciplinary action, or further investigation.~~

~~(d) CQRP report procedures:~~

~~(1) At the conclusion of the CQRP hearing the panel shall prepare a written report based on the evidence presented at the panel hearing with specific recommendations regarding the licensee and/or the licensee's practice.~~

~~Panel recommendations are the following:~~

~~(A) Continuing education seminars in related field;~~

~~(B) Recommendations that would strengthen aspects of licensee's chiropractic practice;~~

~~(C) Further investigation;~~

~~(D) Refer case to Office of Attorney General for preparation of formal disciplinary action;~~

~~(E) Close case with warning;~~

~~(F) Close case without warning;~~

~~(G) Dismiss complaint.~~

~~(2) The report and recommendations shall go directly to the board's Executive Officer.~~

~~(3) Any departure from accepted chiropractic procedures or practices shall be outlined in this written panel report with the recommendations from subsection (d)(1)(A)-(G) deemed necessary by a vote of a majority of the three member panel.~~

~~(4) All panel recommendations are subject to approval by the board's Executive Officer without further input from the licensee. The Executive Officer shall prepare a final report, which shall include all approved recommendations, and send a copy of the final report to the licensee and panel members.~~

~~(5) The evidence presented at the panel hearing shall be submitted to the board office. All evidence used by the panel is admissible in any subsequent disciplinary proceeding against a licensee.~~

~~(e) The procedures for appealing the final CQRP report are as follows:~~

~~(1) The panel report is reviewed by the board's Executive Officer. After the review, the final report is sent to the licensee. The licensee has 30 days from receipt of the report to file a written appeal with the board.~~

~~(2) The appeal shall be considered by a committee of the board consisting of no more than three members.~~

~~(3) If the committee grants the appeal a final decision shall be prepared and returned to the Executive Officer for distribution to the licensee and panel members.~~

~~(4) If the board's committee denies the appeal, the final report becomes a final decision after 30 days.~~

~~(5) The licensee may appeal the final decision by filing a writ of mandate pursuant to California Code of Civil Procedure, Section 1094.5. The writ of mandate shall be filed in a Superior Court in Los Angeles, San Francisco, or Sacramento counties.~~

~~NOTE: Authority cited: Sections 1000-4(b), 1000-4(c), 1000-4(d), 1000-4(e), and 1000-10(a), Business and Professions Code (Chiropractic Imitative Act). Reference: Sections 1000-4(h), 1000-6(a), Business and Professions Code.~~

History:

1. New section filed 5-13-93; operative 6-14-93 (Register 93, No. 20)
2. Change without regulatory effect amending first paragraph and subsections (a) (2), (c) (8) – (9), (d) (2), (d) (4), (e) (1) and (e) (3) filed 10-5-2007 pursuant to section 100, title 1, California Code of Regulations (Register 2007, No. 40.

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Review of Oral and Written Comments Received for Proposed Regulations Relating to Manipulation Under Anesthesia (MUA) and the Standard of Care

Background:

On April 17, 2007, the Board of Chiropractic Examiners (Board) reaffirmed previous Boards' long standing position that MUA is within the scope of practice of a licensed doctor of chiropractic. The Department of Consumer Affairs (DCA), Division of Legal Affairs, confirmed the Board's position in a legal opinion dated December 13, 2007.

Following the release of the DCA legal opinion affirming that MUA is within the scope of practice of a licensed doctor of chiropractic, the Board voted to adopt standard of care and procedure regulations for licensed doctors of chiropractic to follow when performing MUA.

The Board believes that these safety regulations are critical to ensure the health and safety of the consuming public. The Board approved draft regulations at its November 20, 2008, public meeting, and Board staff filed the corresponding rulemaking package with the Office of Administrative Law on December 30, 2008. Board staff convened the public hearing on February 24, 2009.

Action Requested:

This requests that the Board review and consider the public comments received during the 45-day comment period then determine if it wants to make modifications to the originally proposed language (Attachment A).

Summary of Oral Comments Received at the Public Hearing:

- Mark Singleton. M.D. opposes the proposed regulation and stated that the American Society of Anesthesiologists adopted an official policy statement in 2007 that "declares that the use of general anesthesia for chiropractic spinal manipulation has no scientific basis and there is no evidence to support a claim that its use is either safe or beneficial for patients".

- Charles Davis, D.C., President, International Chiropractors Association, supports the proposed regulations. Dr. Davis, D.C. stated that it has been determined that MUA is within the scope of practice of chiropractors. Chiropractors are trained in MUA more than any other profession. This procedure is used on patients with chronic pain and is safe. It has saved patients from further types of procedures such as surgery. The proposed action is necessary to ensure that MUA is performed in the proper setting and is needed for the protection of the public.

- Kristine Shultz, California Chiropractic Association, (CCA) stated that CCA is in full support of the proposed regulation and believes that is necessary to clarify that the provisions within the chiropractic scope of practice that prohibits the use of drugs only applies to the chiropractor and not to any other health care provider. MUA is an important procedure to have available to patients and without the proposed regulation there are no safety standards in place for this procedure.

- Ed Cremata, D.C. strongly supports the Board's proposed regulation and requests that it is adopted as currently written. Dr. Cremata, D.C. stated that the question has been about safety, which is what the regulation is all about. The intent of Section 318.1 (a) is to ensure public safety by providing mandatory standards for MUA performed by chiropractors. Dr. Cremata, D.C. stated that he has been involved in about 1000 cases with a safety record of zero complications, in part due to the fact that they have always practiced in compliance with mandates of this regulation and in a licensed surgery center. This has not always been the case for MUA practitioners and is pleased that the Board is addressing this in our state. Section 318.1 (b) is also about safety and clarifies the role of the medical physician and chiropractors to ensure there is no confusion or over lap between the duties and limitations of the medical and chiropractor doctors. Section 318.1 (c) is also about safety to address confusion among medical physicians, chiropractors, and staff regarding the need for two doctors to be appropriately trained and to safety provide this procedures. Section 318.1 (d) is also about safety to ensure that patients are properly discharged following the procedure. Section 318.1 (e) mandates compliance with this regulation and allows for the Board to take appropriate disciplinary action, if appropriate. Section 318.1 (f) clearly defines MUA to ensure uniformity and communication on MUA. Lastly, Dr. Cremata, D.C. is surprised by the comments regarding the concern of safety presented at the public hearing because that is clearly what the proposed regulation is all about.

- Roger Calton, Attorney, practices in the field of health care law and has also been involved in chiropractic education for several years. Mr. Calton stated that after further research, he determined that MUA is within the scope of practice of chiropractors and does not violate Section 7 of the Act. This is also stated in the Department of Consumer Affairs, Division of Legal Affairs legal opinion dated December 13, 2007. Mr. Calton supports the proposed regulations and provided an article from South Florida Sun-Sentinal (copy enclosed) about a patient that was severally injured during an MUA procedure due to the lack of oxygen administered by a medical doctor. The medical doctor that performed the procedure did not properly monitor the patient's oxygen level nor did the surgery room have a working oxygen supply. The article revealed that the center managers failed to check doctors' credentials to perform procedure, the surgery failed to have the proper oxygen, and failed to have written safety procedures. In this particular case, it was not the MUA that was the problem it was the medical doctor that failed to properly monitor the patient under anesthesia. Mr. Calton stated that this case illustrates the need for this regulation and such safety regulations would have prevented this patient's injuries. Mr. Calton wants to ensure that MUA is performed in a quality setting and in the right way.

- Lou Ringler, President, California Academy for MUA, supports the proposed regulation and hopes that the regulation is adopted. Mr. Ringler stated that he was asked by several chiropractors to conduct research on MUA and bring training programs into California. It took two (2) years to conduct the efficacy and safety factors of MUA.

The Board has approved Mr. Ringler as an approved continuing education provider of MUA since 1998. Mr. Ringler is not aware of a single incident of malpractice relative to MUA.

Written Comments Received During the 45-day comment period:

- William E. Barnaby, California Society of Anesthesiologists, Legislative Counsel, opposes the proposed regulations in its entirety. Mr. Barnaby states that the proposed action is not consistent with Section 7 of the Initiative Act (Act), which prohibits the use of any drug or medicine in the practice of chiropractic.

- Michael Champeau, President, California Society of Anesthesiologists, opposes the proposed regulations. Mr. Champeau states that the proposed action violates Section 7 of the Act because it does not allow the use of any drug or medicine now or hereafter included in material medica. Mr. Chapeau also stated that the proposed regulations do not define MUA; therefore, it fails to meet the required standards of consistency and clarity. Without an MUA definition, it is not apparent that MUA uses drugs as an integral part of the chiropractic procedure, in order to achieve physiologic change in the condition of the body tissues being manipulated.

- Kathleen S. Creason, Executive Director, Osteopathic Physicians and Surgeons of California, opposes the proposed regulations because chiropractors do not have the legal authority to perform MUA and she is concerned with patient safety.

- David Ninan, DO, Chair, Department of Anesthesia, opposes the proposed regulation because it is outside the scope of practice of chiropractic care, and he is concerned about the safety of patients who undergo MUA.

- Delilah Clay, Research Associate, Medical and Regulatory Policy, California Medical Association, opposes the proposed regulations because MUA does not fall within the chiropractic scope of practice and is inconsistent with the statutory and initiative measure. Ms. Clay commented that subdivision (a) is problematic because is inconsistent with current California law. Hospitals are not accredited by the organizations listed in the regulations and ambulatory surgical center may be accredited, but only by those that are deemed to be accrediting organization approved by the Medical Board of California. Subdivision (b) is unclear as to who may perform such anesthesia and under what circumstances.

- Barb Johnston, Executive Director, Medical Board of California (MBC), has a concern with Section 318.1 (a) of the proposed regulations. Physicians placing patients under anesthesia must, by law (section 2216 of the Business and Professions Code (B&P), perform the procedure in settings listed in Section 1248.1 of the Health & Safety Code. To place patients under anesthesia outside of the listed settings is unprofessional conduct and the basis for disciplinary action (B&P 2216.1). Section 318.1 (a) lists approved agencies; however, it lists Det Norske Veritas Healthcare Incorporated, which has never applied for approval and does not appear to fit in any of the settings permitted by Section 1248.1. Therefore, physicians would not be in compliance with the law if the only accreditation granted to a facility was by that organization. The MBC requests that the Board amend the proposed language to rectify this problem. The MBC has the statutory authority to issue only plenary licenses, an absolute license pursuant to which any licensee can practice any specialty of medicine and should be noted in Section 318.1 (b) the same of chiropractors who will be performing MUA.

B&P Section 2242 requires a patient to have an appropriate examination prior to prescribing, dispensing, or furnishing dangerous drugs. To be consistent with the Medical Practice Act, this requirement should be included in the proposed language.

Copies of all written comments are included in Attachment B.

The following individuals provided written comments in support of the proposed regulations:

- Robert S. Francis, D.C.
- Diane Grant Zollweg
- Annette K. Cassity, D.C.
- David Benevento, D.C., President, California Chiropractic Association
- Charles Davis, D.C., President, International Chiropractors Association

Board Staff Comments:

Staff disagrees with those who provided oral and written comments opposing the proposed regulations based solely on the opinion that MUA is not within the scope of practice of a licensed doctor of chiropractic. The Board resolved the scope of practice question with the DCA legal opinion. These proposed regulations simply state where, how, and who should perform MUA in order to protect the public.

Further, Board staff disagrees with the comments that the proposed regulations fail to meet the standards of clarity, necessity, and consistency required by the Administrative Procedures Act. The purpose of the proposed regulations is to identify and distinguish the responsibility of the anesthesiologist and licensed doctors of chiropractic performing MUA and to ensure the protection of the patient undergoing MUA.

Board staff agrees with the MBC's recommendations to amend the proposed language to require an examination to be completed prior to the MUA procedure and to clarify the proper setting where the procedure shall take place.

Board Staff Recommendations:

Board staff recommends that the Board adopt a modification to the proposed language to include the MBC's recommendations. The proposed modifications to the original language are contained in Attachment C.

Attachment A

Proposed Regulatory Language for MUA

Section 318.1 is hereby added to Title 16, Division 4, Article 2 of the California Code of Regulations:

318.1 **Standard of Care re Manipulation Under Anesthesia (MUA)**

(a) MUA may only be performed in a hospital or ambulatory surgery center that is licensed by the California Department of Public Health, Bureau of Hospital Licensing and Certification or a hospital or ambulatory surgery center that is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the American Association for Accreditation of Ambulatory Surgery, the Accreditation Association for Ambulatory Health Care, Medicare, Det Norske Veritas Healthcare Incorporated, or the Institute for Medical Quality. If any of the above named organizations changes its name the Board shall continue to recognize the organization.

(b) Anesthesia may only be administered by a California licensed physician and surgeon, or other health care provider authorized under California law to administer anesthesia. The chiropractor may not direct, instruct, interfere, or make any orders to the physician and surgeon, or other health care provider who is administering and maintaining the anesthesia.

(c) MUA shall be performed by two chiropractors trained and competent to safely perform MUA. The "primary chiropractor" shall formulate the chiropractic portion of the MUA treatment plan and shall be responsible for performing the chiropractic manipulation for that procedure. The "second chiropractor" shall insure that all movements are accomplished with patient care and safety as his or her primary focus and shall assist the "primary chiropractor" when necessary. The chiropractic portion of MUA is limited to techniques within the scope of practice of a chiropractor.

(d) For the purpose of this section, the primary chiropractor and the second chiropractor may not be involved in nor interfere with the physician and surgeon or other health care provider in the discharge of the patient following the MUA procedure.

(e) Failure to follow the standard of care contained in this section when performing MUA shall constitute unprofessional conduct.

(f) MUA means the manipulation of a patient who is sedated by the administration of anesthesia by a physician and surgeon or other health care provider who is legally authorized to administer anesthesia.

Attachment B

Written Comments

- February 11, 2009, Robert S. Francis, DC
- February 12, 2009, South Florida Sun-Sentinel Article
- February 15, 2009, Diane Grant Zollweg
- February 18, 2009, Barb Johnson
- February 21, 2009, Charles Davis
- February 23, 2009, William E. Barnaby and William E. Barnaby III
- February 23, 2009, Kathleen S. Creason, MBA
- February 23, 2009, David Ninan, DO
- February 24, 2009, Delilah Clay
- February 24, 2009, David Benevento, DC
- Undated, Annette K. Cassity, DC

Robert S. Francis, D.C.
Clinical Assistant Professor of Family Medicine
Department of Family Medicine
University of Texas Medical Branch
Visiting Professor,
St. George's University School of Medicine

7119 Trimstone Drive
Pasadena, Texas 77505

Office: 281-998-9454 Email: Fax: 281-998-3338

February 11, 2009

BCE-MUA REG PROPOSAL
ATTENTION: April Alameda, Program Analyst
2525 Natomas Park Drive, Suite 260
Sacramento, California 95833

Re: Proposed MUA Regulations

Dear Ms. Alameda,

Please allow this letter to express and convey my opinions regarding the BCE's proposed regulation language changes related to Manipulation Under Anesthesia.

I have had the opportunity to review the BCE's proposed regulation language changes for manipulation under anesthesia. My professional opinions are based upon those proposed changes, my experience in developing the first certification course for MUA procedures under the auspices of Texas Chiropractic College while serving as Academic Dean. I have taught MUA certification courses for more than twenty-five years around the United States and in Europe. My clinical experience as a private practitioner, Dean of Clinical Sciences, Director of Institutional Research, contributor to Standard of Care publications, and my academic appointments, publications and didactic and clinical presentations provide me with a unique perspective to review these regulations and to opine favorably in the proposed language.

This regulation is made necessary because MUA should only be performed in a hospital or ambulatory surgical center and specific setting regulations are appropriate for

the performance of these procedures. These settings should be well identified and clarified in the regulation.

Since the BCE is charged with and has the authority to regulate the practice of chiropractic and foremost to protect the interest of health care consumers in that regard, the need to promulgate further MUA regulations is appropriate.

Specifically the BCE prohibits the administration or prescription of drugs by chiropractors. In the interest of consumer protection, it is appropriate and necessary that the BCE clarify and delineate specifically that chiropractors are prohibited from administering drugs or interfering with or directing the physician who is administering or prescribing drugs during the MUA procedures towards an effort to be consistent with existing statutes.

It is the BCE's primary responsibility to protect the health and safety of the public and to ensure that consumers of chiropractic care during MUA procedures receive the highest quality care. It is therefore necessary to clarify and specifically describe that the purpose and requirement for two chiropractors to perform this procedure is to ensure the protection, health and safety of the patient and the highest and best delivery of service.

All patients must be discharged from the facility where the MUA procedures are performed by appropriate physician staff. It is therefore necessary that the BCE specifically prohibit chiropractors from discharging patients from the facility in order to ensure that the patient receives the appropriate care required before a patient is safely discharged following anesthesia.

It is necessary for the BCE under its statutory authority to define the scope of practice of chiropractic and to regulate chiropractors who provide MUA services under BCE auspices to be clearly aware of the definition of MUA procedures as set forth by the BCE specifically for purposes of defining exactly what MUA constitutes.

It is clearly necessary for BCE to adopt this regulation language change to specify that there are no other inconsistent statutes, court decisions or other provisions of law and that this language is consistent with all other statutory provisions in that regard.

It is widely held that MUA is a common procedure used by several medical specialties. Manipulation under anesthesia is not considered investigational nor experimental.

The AMA does not consider MUA to be investigational or experimental because it has assigned CPT codes for the MUA procedures since 1971. The AMA does not assign CPT codes for investigational or experimental procedures. Regulatory agencies license chiropractors to perform the procedure as a well documented and accepted procedure in the mainstream medical community. Universities and colleges sponsor certification courses as well as continuing education courses in manipulation under anesthesia in many states around the United States as well as in Europe. Hospitals and ambulatory surgical centers credential chiropractors with clinical privileges on the medical staff to perform manipulation under anesthesia. These facilities are accredited by local, state and federal accreditation agencies to do so. And finally, malpractice carriers provide liability coverage for manipulation under anesthesia because it is a well documented, usual and customary procedure within the commonly accepted clinical practices of licensed and duly certified chiropractors.

Manipulation under anesthesia is well documented in the medical literature. Numerous studies suggest the efficacy and safety of manipulation under anesthesia for properly selected patients over the past several decades. One such review was published in a peer-reviewed medical publication, THE SPINE JOURNAL in 2002. The authors performed a literature review of manipulation under anesthesia (49 published articles) and concluded that manipulation under anesthesia procedures have a relatively long history of clinical use and have been reported in the literature for over 70 years based on case series in the same fashion as many other accepted surgical and conservative approaches for the treatment of chronic pain syndromes of musculoskeletal origin.

MUA procedures enjoy the recognition of clinical efficacy among many medical disciplines as witnessed by the recent multi-disciplinary clinical MUA textbook published in March, 2005, regarding the acknowledgment of the clinical effectiveness of manipulation under anesthesia outlining the safety, clinical efficacy, utilization protocol, and clinical studies supporting manipulation under anesthesia. Many of the authors of this publication hold academic appointments at reputable medical schools, chiropractic colleges and universities.

This textbook is universally recognized in the chiropractic profession as the most comprehensive single publication for MUA procedures and as such is utilized for clinical

and didactic training in every recognized MUA certification course in the US and in Europe.

I strongly urge your favorable consideration of the MUA regulation proposal.

Sincerely,

Robert S. Francis, D.C.

sun-sentinel.com/business/sfl-bn-0212-medcenter,0,462292.story

South Florida Sun-Sentinel.com

State bars new patients from Pompano Beach surgery center

By Bob LaMendola

South Florida Sun Sentinel

5:32 PM EST, February 12, 2009

POMPANO BEACH

State officials have effectively shut down a Pompano Beach outpatient surgical center that inspectors found to be poorly run after a man fell into a coma during a procedure, records show.

Atlantic Surgical Center was forbidden from seeing new patients as of Feb. 5, the same day as an emergency inspection by the Florida Agency for Health Care Administration, an agency order and report show.

The patient, Dale Whyte, 33, stopped breathing while under sedation during a Dec. 4 joint manipulation procedure and was rushed to North Broward Medical Center in Deerfield Beach, where he has been virtually unresponsive, said Bob Kelley, an attorney for Whyte's family.

The state report said Whyte suffered an apparent heart attack, but Kelley said it's not clear what happened.

"He was deprived of oxygen. He is severely brain damaged," Kelley said. "It's horrible. He was a perfectly healthy man."

In response to a complaint about the case, state inspectors went to the surgery center and reported that the doctors involved did not properly monitor the man's oxygen level, and the surgery room did not have a working oxygen supply.

The report said that the center managers had not checked doctors' credentials to perform procedures, had no written patient-safety program and had not had a medical director since October to oversee medical care.

After the incident, the manager resigned and the center has done nothing to investigate or fix any problems.

"Systems created and designed to guarantee patient safety are not in place and not being employed," agency officials said in the report.

Andrew Byers, who is listed in state records as administrator and corporate director for the center, could not be contacted for comment.

Kelley said Whyte, a father of two pre-schoolers, underwent "manipulation under anesthesia," in which joints are strenuously flexed and stretched while the patient is unconscious. He said manipulations were planned for Whyte's spine, pelvis, hips, shoulders and limbs.

Kelley said the physicians involved were Dr. Basil Mangra of Lauderdale Lakes and anesthesiologist Thomas Rodenberg of Fort Lauderdale. Neither could be contacted for comment.

Bob LaMendola can be reached at blamendola@SunSentinel.com or 954-356-4526 or 561-243-6600, ext. 4526.

February 17th, 2009

THIS WEEK'S ARTICLES

LAST WEEK'S E-WEEKLY ARTICLES
SCHIP Bill Leaves Physician Ownership Alone
Anesthesiologist Arrested for Vandalism, Illegals
Video Laryngoscopy to Prime Time
News & Notes

Florida Inspectors Close ASC

A Pompano Beach, Fla., surgery center was ordered closed and barred from treating new patients after state inspectors discovered serious mismanagement during an emergency survey.

Officials from the Florida Agency for Health Care Administration visited the Atlantic Surgery Center on Feb. 5 in response to complaints about a December incident in which a patient fell into a coma while under anesthesia.

According to a published report, Dan Whyte, 33, was undergoing a joint manipulation procedure for which he'd been sedated when he stopped breathing. He was taken to North Broward Medical Center in Deerfield Beach, where he remains unresponsive.

Not only did attending physician Basil Mangra, MD, and anesthesiologist Thomas Rodenberg, MD, fail to monitor the patient's oxygen level, reported the inspectors, but the room in which the procedure took place did not have a working oxygen supply.

In addition, the center's managers were lax in verifying its physicians' credentials, it had no written patient safety protocol and its medical director position had been vacant since October, the report says.

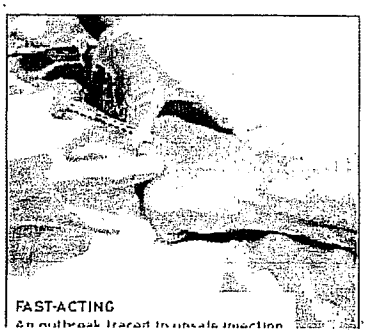
David Bernard

^ Back to Top

Accreditors Team Up with Nevada for Patient Safety

In the wake of last year's hepatitis C outbreak, the Joint Commission, the Accreditation Association for Ambulatory Health Care and other healthcare industry authorities plan to report patient safety breaches to the Nevada Department of Health and Human Services.

For its part, the Joint Commission will report patient safety issues within two days of discovery and share its schedule of unannounced visits with the health department, according to a published report.



FAST-ACTING
An outbreak traced to unsafe injection

February 3rd E-WEEKLY
Study: Health IT Improves Patient Outcome
Ortho Patients' Pain Matches Their Expectations
Spine Society Requires Financial Disclosure
News & Notes

advertisement

January 27th E-WEEKLY
Joint Commission Site Hosts Patient Satisfaction Data
Cash-strapped Hospitals Put Needed Improvements on Hold
Partial Knee Replacement More Than a Quick Fix
Instapoll: Accreditation Surveyors Generally Thorough, Fair
News & Notes

AARP Bulletin today

State says outpatient surgical center in Pompano Beach can't see new patients

Source: Ft. Lauderdale Sun-Sentinel | February 13, 2009

State officials have effectively shut down a Pompano Beach outpatient surgical center that inspectors found to be poorly run after a man fell into a coma during a procedure, records show.

Atlantic Surgical Center was forbidden from seeing new patients as of Feb. 5, the same day as an emergency inspection by the Florida Agency for Health Care Administration, an agency order and report show.

The patient, Dale Whyte, 33, stopped breathing while under sedation during a Dec. 4 joint manipulation procedure and was rushed to North Broward Medical Center in Deerfield Beach, where he has been virtually unresponsive, said Bob Kelley, an attorney for Whyte's family.

The state report said Whyte suffered an apparent heart attack, but Kelley said it's not clear what happened.

"He was deprived of oxygen. He is severely brain damaged," Kelley said. "It's horrible. He was a perfectly healthy man."

In response to a complaint about the case, state inspectors went to the surgery center and reported that the doctors involved did not properly monitor the man's oxygen level, and the surgery room did not have a working oxygen supply.

The report said that the center managers had not checked doctors' credentials to perform procedures, had no written patient-safety program and had not had a medical director since October to oversee medical care.

Andrew Byers, who is listed in state records as administrator and corporate director for the center, could not be contacted for comment.

Kelley said Whyte, a father of two preschoolers, underwent "manipulation under anesthesia," in which joints are strenuously flexed and stretched while the patient is unconscious. He said manipulations were planned for Whyte's spine, pelvis, hips, shoulders and limbs.

Kelley said the physicians involved were Dr. Basil Mangra of Lauderdale Lakes and anesthesiologist Thomas Rodenberg of Fort Lauderdale. Neither could be contacted for comment.

Bob LaMendola can be reached at blamendola@SunSentinel.com or 954-356-4526 or 561-243-6600, ext. 4526.

February 15, 2009

To Whom It May Concern,

This has been an unusually challenging year for me, beginning with a fall from a stepladder onto my driveway, April 10, 2008. The injuries sustained that day were numerous, however, the greatest damage was to my right shoulder area. An MRI disclosed a full thickness tear of my right rotator cuff.

Before surgical repair could take place my orthopedic surgeon, Dr. Kent Adamson, of Community Orthopedic Medical Group, Mission Viejo, CA, required that I achieve increased range of motion with my right arm and shoulder. This request was understandable as I could not lift my elbow away from my waist. The task soon became impossible however as I developed what is known as a frozen shoulder. At this point my surgeon suggested that I have a procedure known as an MUA (manipulation under anesthesia), to free the restriction in my shoulder. Dr. Adamson said that this procedure would save me many months of inactivity, restriction & pain. At this point I had already experienced many months of inactivity, restriction & pain, so I decided that this was a viable option in treating my shoulder.

Dr. Jeff Hedgecock, owner of Newport Crest Medical Center, Newport Beach, CA, my chiropractor/physical therapist, preformed 2 MUA's for me in July and August. Each time these procedures resulted in immediate and substantial freedom of movement, along with easing of pain. These two MUA's, along with ongoing physical therapy, allowed me to undergo the needed surgical repair to my right shoulder in October.

Recovery from this injury has been a long and arduous journey. One can only guess how much longer and more painful this ordeal would have been without the MUA's being utilized in my treatment. I, for one, am very grateful this procedure was offered and available to me. The manipulation under anesthesia is a tool that helped to expedite my treatment and recovery.

Sincerely,

Diane Grant Zollweg

MEDICAL BOARD OF CALIFORNIA
Executive Office

BOARD OF CHIROPRACTIC EXAMINERS
09 FEB 19 PM 12:50

February 18, 2009

April Alameda, Program Analyst
Board of Chiropractic Examiners
2525 Natomas Park Drive, Suite 260
Sacramento, California 95833

Proposed Rulemaking: Standards of Care re Manipulation Under Anesthesia (MUA)

Dear Ms. Alameda:

The Medical Board of California (Medical Board) appreciates the opportunity afforded by the Board of Chiropractic Examiners to review the proposed rulemaking addressing the "Standards of Care re Manipulation Under Anesthesia (MUA)" and we would like to share our concerns.

Section 318.1 (a):

The Medical Board has a concern about Section 318 (a) of the proposed regulation. Physicians placing patients under anesthesia must, by law (Section 2216 of the Business & Professions (B&P) Code), perform the procedure in settings enumerated in Section 1248.1 of the Health & Safety (H&S) Code. To place patients under anesthesia outside of these enumerated settings is unprofessional conduct and the basis for disciplinary action. (B&P 2216.1)

H&S Code Section 1248.1 enumerates those practice settings which, by virtue of their location, how they were created, or by whom they are operated, are eligible practice settings.

Notwithstanding the aforementioned section, H&S Code Section 1248.1 requires that "general" anesthesia must be induced only in the settings described in that sections, which includes facilities accredited by an agency approved by the Medical Board. To date, the Medical Board has approved the following agencies:

* American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
* Accreditation Association for Ambulatory Health Care (AAAHC)
* The Joint Commission (formerly known as the Joint Commission on the Accreditation of Healthcare Organizations [JCAHO])
* The Institute for Medical Quality (IMQ)

Section 318.1 (a) lists the above agencies, as well as Det Norske Veritas Healthcare Incorporated. Det Norske has never applied for approval and does not appear to fit in any of the settings permitted by Section 1248.1. Therefore, physicians would not be in compliance with the law if the only accreditation granted to a facility was by that organization. Therefore, we request that this be amended to read:

> (a) MUA may only be performed in a hospital or ambulatory surgery center that is licensed by the California Department of Public Health, Bureau of Hospital Licensing and Certification or ~~a hospital or~~ in an ambulatory surgery center operating pursuant to Section 1248.1 of the Health and Safety Code or that is accredited by ~~the Joint Commission on Accreditation of Healthcare Organizations, the American Association for Accreditation of Ambulatory Surgery, the Accreditation Association for Ambulatory Health Care, Medicare, Det Norske Veritas Healthcare Incorporated, or the Institute for Medical Quality. If any of the above named organizations changes its name the Board shall continue to recognize the organization.~~ an agency approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and Safety Code (commencing with Section 1248).

This amendment would remove Det Norske Veritas Heathcare Incorporated from the regulation, an agency that is not an approved accreditation agency. In addition, this amendment would not need to be revised at a later date should new agencies be approved or approved agencies be revoked, or, as in the case of the Joint Commission, there are name changes for the agencies.

Section 318.1 (b):

The Medical Board has the statutory authority to issue only plenary licenses, an absolute license pursuant to which any licensee can practice any specialty of medicine. Nevertheless, it is in the greatest interest of consumer protection that licensees only work in the area in which they have been trained and are competent. It should be noted that Section 318.1 (c) requires the same of the chiropractor who will be performing the MUA.

Further, B&P Code Section 2242 states that "Prescribing, dispensing, or furnishing dangerous drugs . . . without an appropriate prior examination . . . constitutes unprofessional conduct." In a traditional medical setting, the physician administering the anesthesia already is working in concert with the patient's primary care physician or specialist. However, in the setting contemplated by this rulemaking, such medical oversight by a primary care physician or specialist is absent. Therefore, to ensure consistency with the Medical Practice Act, this requirement should be included in the proposed regulation.

Therefore, we suggest that this be amended to read:

> (b) Anesthesia may only be administered, following an appropriate prior examination, by a California physician and surgeon trained and competent to administer anesthesia safely, or other health care provider authorized . . .

If we may be of further assistance, please contact Kevin A. Schunke, Regulations Manager, at (916) 263-2368 or via email at: kschunke@mbc.ca.gov.

Sincerely,

Barb Johnston
Executive Director

ICAC ON CHIROPRACTIC MANIPULATIVE THERAPY - FEB 2009

CHIROPRACTIC MANIPULATIVE THERAPY

We found no evidence of excess risk of VBA stroke associated chiropractic care.

• Cassidy JD, Boyle E, Cote P, et al. Risk of vertebrobasilar stroke and chiropractic care: results of a population-based case-control and case cross over study. Spine 2008;33:S176-S83.

Safety & Effectiveness

The best evidence indicates that cervical manipulation for neck pain is much safer than the use of NSAIDs, by as much as a factor of several hundred times.

There is no evidence that indicates NSAID use is any more effective than cervical manipulation for neck pain.

Dabbs V, Lauretti WJ. A risk assessment of cervical manipulation vs. NSAIDs for the treatment of neck pain. J Manipulative Physiol Ther. 1995 Oct;18(8):530-6.

A number of alternative and complementary medicine interventions have more evidence of efficacy than conventional medical care.

• Guzman J, Haldeman S, Carroll LJ, Carragee EJ, Hurwitz EL, Peloso P, Nordin M, Cassidy JD, Holm LW, Côté P, van der Velde G, Hogg-Johnson S; Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. Clinical practice implications of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders: from concepts and findings to recommendations. Spine. 2008 Feb 15;33(4 Suppl):S199-213.

What group of profession health care providers performs manipulative therapy?

94% of the manipulative therapy performed in the United States is by chiropractors.

Shekelle PG, Adams AH, Chassin MR, Hurwitz EL, Brook RH. Spinal manipulation for low-back pain. Ann Intern Med 1992;117:590–8.

As part of chiropractic education there are over 600 hours of basic instruction for manipulative therapy with an additional 8 months of internship.

Therefore, if anyone is going to do a spinal manipulative procedure, then it should be done by a chiropractor, and this procedure is within the scope of practice of a chiropractor in the state of California.

NCMIC (The largest Chiropractic Malpractice Insurance Company) does not charge an additional premium for the MUA Endorsement.

Pi Omege Delta in 10+ years of this known activity in chiropractic, we have not had a single claim or paid loss as a result of MUA.

Manipulation Under Anesthesia performed by chiropractic doctors is safe and effective.

MEDICAL TREATMENT ALTERNATIVES

1. 60% of spinal fusion patients will continue to suffer from back pain. A full recovery cannot be predicted.
2. 30% of patients will be neither better nor worse because the pain does not emanate from the segment that has been fused!
3. 10% are distinctly worse for having a failed fusion.
4. In 10-20% of cases the bone graft fails to unite completely *leaving a permanent pseudoarthrosis.*
5. In cases of prolapsed discs and sciatica, 65% of patients will continue to experience post-operative back pain.
6. A dural tear occurs in 3-5% of lumbar spine operations.
7. Pedicle screws are inserted in fusion using a 3.5mm bit and a depth gauge; in 12-21% of screw placements, *the pedicle is transgressed and the peripheral cortex is broken.*
8. Postoperative infection developed in 4.4%. Spine. 2005 Jun 15;30(12):1460-5.
9. Overall the incidence of dysphagia 2 years after anterior cervical spine surgery was 13.6% Lee MJ, Bazaz R, Furey CG. Risk factors for dysphagia after anterior cervical spine surgery: a two-year prospective cohort study. Spine J. vol. 7, 141 - 147, 2007
10. Complication rates for revision lumbar surgery in this series were 3 to 5 times higher than reported for primary lumbar exposures. Spine. 2009 Jan 1;34(1):87-90.
11. 6% of surgically treated patients had recurrent sciatica that led to a second surgical intervention during the two years of follow-up. BMJ 14 June 2008.vol 336 p 1355-1358

Comparison of Risk

Procedure or Activity	Estimated Risk	Source
Risk of death in fatal air crash, flying three hours on a U.S. commercial airline	1 in 2,000,000	(12)
Risk of death in motor vehicle accident, driving 35 miles	1 in 2,000,000	(13)
Risk of serious stroke or neurological complication resulting from a chiropractic neck adjustment treatments	1 in 2,000,000 Range from 1:500,000 to 1:5,000,000	(14-16)
Risk of being injured in motor vehicle accident, driving ½ mile	1 in 2,000,000	(12)
Risk of death, per year, from GI bleeding due to NSAID use for osteoarthritis and related conditions	800 in 2,000,000	(17)
Overall Mortality rate for spinal surgery	7 in 10,000	(18)
Death rate from cervical spine surgery	4-10 in 10,000	(19)
Rate of serious or life-threatening complications from spinal stenosis surgery	5 in 100	(18)
Risk of a developing a gastric ulcer visible on endoscopic examination after 1 week's treatment with naproxen (at 500mg twice daily	19 in 100 (380,000 in 2,000,000)	(19)

12. Based on 1997-2000 Transportation Statistics showing an average of 1.57 deaths per 1,000,000 flight hours http://www.bts.gov/publications/nts/
13. Based on 1.5 deaths per 100 million vehicle miles and 116 injuries per 100 million miles traveled in 2000: Traffic Safety Facts 2000. National Highway Traffic Safety Administration http://www.nhtsa.dot.gov/.
14. Terrett AGJ: Current Concepts in Vertebrobasilar Complications following Spinal Manipulation. West Des Moines, IA: NCMIC Group, Inc., 2001.
15. Klougart N, Leboeuf-Yde C, Rasmussen LR: Safety in chiropractic practice part I: The occurrence of cerebrovascular accidents after manipulation to the neck in Denmark from 1978-1988. J Manipulative Physiol Ther 1996; 19;371.
16. Haldeman S, Carey P, Townsend M, Papadopoulos C: Arterial dissections following cervical manipulation: the chiropractic experience. CMAJ 2001;165:905.
17. Fries JF: Assessing and understanding patient risk. Scan J Rheumatol 1992; suppl. 92:21.
18. Bigos S, Bowyer O, Braen G, et al: *Acute Low Back Problems in Adults.* Clinical Practice Guideline No. 14. Rockville, Maryland, 1994, U.S. Department of Health and Human Services, Public Health.
19. The cervical spine research society editorial committee: *The cervical spine* (2nd edition). New York: J.B. Lippincott Company, 1989.
20. Armstrong CP, Blower AL: Nonsteroidal anti-inflammatory drugs and life threatening complications of peptic ulceration. Gut 1987; 28:527.

Regional Anesthetic Nonvascular Complications (rate per 10,000)

#Subjects	Nerve Injury	Cardiac Arrest	Death
40,640 spinal	5.9	6.4	1.5
30,413 epidural	2	1	0
21,278 PNB	1.9	1.4	0.5

Auroy Y, Narchi P, Messiah A, Litt L, Rouvier B, Samii K. Serious complications related to regional anesthesia: results of a prospective survey in France. Anesthesiology. 1997 Sep;87(3):479-86.

Medical Treatments

The incidence of hospital admission due to major GI events of the entire (upper and lower) gastrointestinal tract was 121.9 events/100,000 persons/year, but those related to the upper GI tract were six times more frequent. Mortality rate was 5.57% (95% CI = 4.9-6.7), and 5.62% (95% CI = 4.8-6.8) in study 1 and study 2, respectively.

Death rate attributed to NSAID/aspirin use was between 21.0 and 24.8 cases/million people, respectively, or 15.3 deaths/100,000 NSAID/aspirin users.

> Lanas A, Perez-Aisa MA, Feu F, Ponce J, Saperas E, Santolaria S, Rodrigo L, Balanzo J, Bajador E, Almela P, Navarro JM, Carballo F, Castro M, Quintero E; Investigators of the Asociación Española de Gastroenterología (AEG). A nationwide study of mortality associated with hospital admission due to severe gastrointestinal events and those associated with nonsteroidal antiinflammatory drug use. Am J Gastroenterol. 2005 Aug;100(8):1685-93.

NSAIDs are the most commonly prescribed medications for neck pain. Approximately 13 million Americans use NSAIDs regularly.

81% of GI bleeds related to NSAID use occur without prior symptoms.

The annual cost of GI tract complications in the US is estimated at $3.9 billion, with up to 103,000 hospitalizations and at least 16,500 deaths per year

> Wolfe M, Lichtenstein D, Singh G. Gastrointestinal Toxicity of Nonsteroidal Antiinflammatory Drugs. NEJM June 17, 1999; 340(24): 1888-99.
>
> Bloom BS. Direct medical costs of disease and gastrointestinal side effects during treatment for arthritis. Am J Med 1988;84(suppl 2A):20-24.

Research in the United Kingdom has shown NSAIDs will cause 12,000 emergency admissions and 2,500 deaths per year due to GI tract complications.

> Blower AL, Brooks A, Fenn GC, Hill A, Pearce MY, Morant S, Bardhan KD. Emergency admissions for upper gastrointestinal disease and their relation to NSAID use. Aliment Pharmacol Ther. 1997 Apr;11(2):283-91.

Epidemiology of medical error

- In the United States medical error results in 44,000- 98,000 unnecessary deaths each year and 1,000,000 excess injuries
- BMJ 2000 VOLUME 320 18 MARCH

Serious Adverse Drug Events Reported to the Food and Drug Administration, 1998-2005

These data show a ***marked increase*** in reported deaths and serious injuries associated with drug therapy over the study period.

From 1998 through 2005, reported serious adverse drug events increased 2.6-fold from 34,966 to 89,842 and fatal adverse drug events increased 2.7-fold from 5,519 to 15,107.

Arch Intern Med. 2007;167(16):1752-1759.

Frequency of Analgesic Use and Risk of Hypertension Among Men

• The frequency of nonnarcotic analgesic use is independently associated with a moderate increase in the risk of incident hypertension.

• Given the widespread use of these medications and the high prevalence of hypertension, these results may have important public health implications.

• Arch Intern Med. 2007;167:394-399.

Association Between Nonsteroidal Anti-inflammatory Drugs and Upper Gastrointestinal Tract Bleeding/Perforation

Relative risk of UGIB after exposure to NSAIDs was 3.8 (95% confidence interval, 3.6-4.1).

Arch Intern Med. 2000;160:2093-2099.

Adverse effects of NSAIDs on renal (kidney) function

A variety of adverse effects of NSAIDs on renal function have been identified.

* Reduction in renal blood flow and the glomerular filtration rate.
* Acute tubular necrosis.
* Allergic interstitial nephritis, with or without accompanying nephrotic syndrome.
* Renal papillary necrosis.
* Water, salt and potassium disturbances.
* Impairment of blood pressure control.

CAN MED ASSOC J, VOL. 131, AUGUST 1, 1984

Analgesic use and chronic renal (kidney) failure: A critical review of the epidemiologic literature

• Since use of analgesics is widespread and new OTC products are introduced frequently, the potential impact of these drugs on the development of chronic renal failure may be significant, thus warranting continued evaluation of these products for any renal toxicity.

• Kidney International, 1998 (54), pp. 679–686.

Renal (kidney) toxic effects are common in high-risk patients receiving celecoxib or diclofenac plus omeprazole.

• N Engl J Med 2002;347:2104-10.

Nonsteroidal Antiinflammatory Drugs, Acetaminophen, and the Risk of Cardiovascular Events

• Use of NSAIDs or acetaminophen at high frequency or dose is associated with a significantly increased risk for major cardiovascular events, although more moderate use did not confer substantial risk.

• A significant dose-response relations: Compared with nonusers, the RRs for a cardiovascular event among women who used 15 tablets per week were 1.86 (95% CI, 1.27 to 2.73) for NSAIDs and 1.68 (95% CI, 1.10 to 2.58) for acetaminophen.

• Circulation. 2006;113:1578-1587.

Non-steroidal anti-inflammatory drugs and life threatening complications of peptic ulceration

- The overall incidence of NSAID use in a hospital control group was 9-9%. The first sign of an ulcer was a life threatening complication in 58*2% of patients taking a NSAID.
- Nearly 80% of all ulcer related deaths occurred in patients using an anti-inflammatory agent.
- Patients using these drugs were older, with more pre-existing medical conditions and had larger ulcers than those not taking NSAIDs.
- The mortality associated with a peptic ulcer complication in patients taking a NSAID was more than twice that in patients with no such drug history.
- There appears to be a relationship between the development of a life threatening complication of peptic ulceration and NSAID ingestion.
- Gut, 1987, 28, 527-532.

Risk of Kidney Failure Associated With the Use of Acetaminophen, Aspirin, and Nonsteroidal Anti-inflammatory Drugs

- Heavier acetaminophen use was associated with an increased risk of end-stage renal disease in a dose dependent fashion.
- For those who took more than 5,000 pills containing acetaminophen in their lifetime, their increased risk of end-stage renal disease was 140%. For some, the increased risk of end-stage renal disease was as high as 380%.
- People who often take acetaminophen have an increased risk of end-stage renal disease.
- New England Journal of Medicine December 22, 1994.

Acetaminophen Toxicity in an Urban County Hospital

- Acetaminophen ingestion accounts for 12% of all patients hospitalized with drug overdoses.
- Acetaminophen ingestion accounts for 40% of patients with acute liver failure.
- New England Journal of Medicine October 16, 1997.

UNNECESSARY SURGERY

- Results from the few studies that have measured unnecessary surgery directly indicate that for some highly controversial operations the fraction that are unwarranted could be as high as 30 percent.
- HSR: Health Services Research 24:3 (August 1989) Lucian L. Leape

Barnaby
Governmental
Relations

February 23, 2009

April Alameda, Program Analyst
Board of Chiropractic Examiners
2525 Natomas Park Drive, Suite 260
Sacramento, CA 95833

RE: Manipulation Under Anesthesia (MUA)
Proposed Regulation Adding Section 318.1 to Title 16 of the CA Code of Regulations
California Society of Anesthesiologists

Dear Ms. Alameda:

On behalf of our client, the California Society of Anesthesiologists (CSA), the enclosed statement and attachments are offered as comments relative to the above-cited proposed regulation on Manipulation Under Anesthesia (MUA).

A MUA regulation previously proposed by the Board of Chiropractic Examiners was disapproved by the Office of Administrative Law (OAL) in 2005. The disapproval was based on the failure to comply with the criteria of the Administrative Procedure Act. Even so, also clearly in question then was whether the MUA proposal was consistent with the Chiropractic Initiative Act. .

It is worth repeating the comments of then-OAL Director William Gausewitz regarding the applicability of specific provisions (Section 7) of the Chiropractic Initiative Act. "It (the Act) prohibits the *use* of any drug or medicine in the practice of chiropractic," he stated. "If the use of anesthesia is integral to the performance of MUA, and if anesthesia is a 'drug', it is highly questionable whether the regulation is consistent with the Act's prohibition on 'the *use* of any drug or medicine'".

The medical/chiropractic literature cited in the accompanying CSA materials describe how the sedative and analgesic affects of anesthetics reduce pain and muscle spasms that hinder the effectiveness of manipulation. In short, the physiologic changes produced by anesthesia enable the manipulation to have the intended therapeutic effect. Without anesthesia, MUA would not work as a therapy. Anesthesia is clearly an integral part of MUA. Hence, it envisions the *use* of anesthesia in chiropractic practice which is barred by law.

Section 7 of the Act authorizes licensed chiropractors "to practice chiropractic" but explicitly prohibits the "the practice of medicine" or "the *use* of any drug or medicine". Here, the instant regulation proposes the use of drugs and the use of medical practitioners (physicians) in the practice of chiropractic.

Respectfully submitted,

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February 24, 2009

April Alameda, Program Analyst
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Re: Proposed Regulations, Manipulation Under Anesthesia (MUA)

These comments are submitted on behalf of the California Society of Anesthesiologists. The proposed addition of Section 318.1 addresses the use of "manipulation under anesthesia" ("MUA"} by Board licentiates, permitting this practice under specified conditions. The proposal thus stands in clear violation of permitted scope of practice under the Chiropractic Initiative Act. Section 7 of that Act (Business & Professions Code §1000-7) states that the Act does not authorize "the use of any drug or medicine now or hereafter included in materia medica." The proposed regulation thus appears unlawful on its face. However, the Board contends that it is the anesthesiologist, not the chiropractor, who "uses" anesthesia. The anesthesiologist, of course, risks professional discipline and civil liability if the Board's argument is not valid. In the final analysis, the only issue will be whether or not the proposed regulation purports to authorize the use of drugs by chiropractors. If it does, it is unlawful.

There is no definition or explanation of MUA in the proposed regulation, or in the supporting materials identified by the Board. As a result, the proposed regulation fails to meet requisite standards for consistency, clarity and showing of necessity, and cannot be adopted. These comments will explain MUA, and the fact that it is indeed the chiropractor who uses the drugs being administered.

The Initial Statement of Reasons recites that "The board has taken the position that MUA is within the scope of practice of a chiropractor." However, this bare policy statement is not substantiated by the Board's regulations, and appears to describe an underground regulation, maintained in violation of the APA. There is no reference to MUA in the regulations, and obviously not in the Initiative Act itself.

The proposed regulation violates the requirement for consistency, because it is inconsistent with the express language of the statute upon which the Board's authority depends. As the Board conceded in 2004, when it last proposed a regulation permitting MUA by licentiates, MUA involves the "use" of drugs and medicines. The Board's Notice at that time, in the section titled "Informative Digest/Policy Statement Overview", cited Section 302 of the Board's present regulations, which refers to authorization to

manipulate and adjust the spinal column and other joints, and stated that "there is no prohibition to the *use* of anesthesia to complete these manipulations" (emphasis added).

The proposed regulation further violates the requirement for clarity, because there is no explanation or definition of MUA, beyond the statement that it is the manipulation of a patient under anesthesia. Absent adequate definition, it is not apparent that MUA is the use of drugs as an integral part of the chiropractic procedure, in order to achieve physiologic change in the condition of the body tissues being manipulated.

Subdivision (a) of section 16, Title 1 of the CCR further defines the "clarity" standard in Gov. Code §11340(b) by the presumption of noncompliance if:

1) "the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
2) the language of the regulation conflicts with the agency's description of the effect of the regulation; or
3) the regulation uses terms which do not have meanings generally familiar to those 'directly affected' by the regulation, and those terms are defined neither in the regulation nor in the governing statute; or
4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation;
5) the regulation presents information in a format that is not readily understandable by persons 'directly affected.'"

The Board's failure to incorporate or present information explaining what "MUA" means makes informed interpretation or assessment impossible.

For the same reason, the Board has also failed to meet requirements for demonstrating necessity. Government Code section 11349.1 (a)(1) requires that OAL review all regulations for compliance with the "necessity" standard. Government Code section 11349(a) defines "necessity" to mean ". . . the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purpose of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion." To further explain the meaning of substantial evidence in the context of the "necessity" standard, subdivision (b) of section 1 0 of title 1 of the California Code of Regulations provides

In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:

1) a statement of the specific purpose of each adoption, amendment, or repeal; and

2) information explaining why each provision of the adopted regulations is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An "expert" within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question.

A useful description of the law governing chiropractic practice in California and its interpretation in numerous appellate decisions appears in Attorney General's Opinion CV 75/282, January 21, 1976. As was made clear in Tain v. State Board of Chiropractic Examiners, (2005)130 Ca.App .4th 609. California chiropractors cannot use methods or modalities which were not included in chiropractic practice in 1922:

> "Moreover, as stated before, the limitations of the acts and practices appellants may legally perform under their chiropractic licenses are properly articulated by both Fowler and Crees. The holding of both cases is that section 7 limits authorized chiropractic healing practices to those taught in chiropractic schools at the time of the enactment of the initiative measure (1922) and that authorization cannot be enlarged by any changes of the curricula of those schools. Consequently, chiropractors are confined to the established measures of adjusting the joints by hand, and to incidental mechanical and hygienic measures that do not invade the field of medicine and surgery. (See Crees, supra, 213 Cal.App.2d at pp. 202, 214.)

The absence of any explanation or definition of "MUA" makes it impossible to find that requirements for conformity, clarity, and necessity are met, and conceals the contemplated violation of the Chiropractic Initiative Act. To explain what MUA actually involves, we are attaching articles written by chiropractors, including Board licentiates, who are proponents of the procedure. While it may be surprising that comments opposing adoption of the proposed regulation place articles advocating use of MUA into the record, the record is otherwise devoid of information defining or describing MUA. An article (Attachment "A") in The Spine Journal, Volume 2, Number 4, July 2002, pages 242-255, by F.J. Kohlbeck, a California chiropractor, and Scott Haldeman, licensed in California as both a chiropractor and a physician, freely concedes that use of medication is integral and essential to the procedure, even in the title, which is *"Medication-Assisted Spinal Manipulation".* Four categories of medication-assisted

manipulation were identified: manipulation under general anesthesia or sedation, manipulation under epidural anesthesia with or without epidural steroid injection, manipulation under joint anesthesia/analgesia, and manipulation with injectants, such as steroids or proliferant agents. Three of these categories involve anesthesia. All involve the use of drugs. That component of the procedure cannot be regarded as severable from the services being rendered by the chiropractor. In each case, drugs are *used*, as the Board acknowledged in its Notice, in the section titled "Informative Digest/Policy Statement Overview", when it proposed a MUA regulation in 2004, for their effect on the tissues which are the subject of the manipulation. The use of sedation or anesthesia during chiropractic manipulation transgresses the defining boundary between medical practice and chiropractic.

Adequate and clear explanation by the Board would disclose that anesthesia is used to change the physiologic state of the tissues. An article (Attachment "B") by Robert C. Gordon DC, the executive director of the National Academy of MUA Physicians and the most prominent proponent of this procedure, titled "*An evaluation of the experimental and investigational status and clinical validity of manipulation of patients under anesthesia: A contemporary opinion*", Journal of Manipulative and Physiological Therapeutics, Volume 24, Issue 9, November 2001, Pages 603-611, makes it clear that drugs are used to alter the state of muscles, ligaments and tendons, for the purpose of manipulation. Dr. Gordon explains that "(s)tandard manipulative techniques are used, but the physiologic state of the patient is changed . . ."

Another article (Attachment "C") by Kohlbeck and Haldeman with others, also appearing in the chiropractic Journal of Manipulative and Physiological Therapeutics Vol. 28, Issue 4, Pages 245-252 (May 2005), titled "*Supplemental Care With Medication-Assisted Manipulation Versus Spinal Manipulation Therapy Alone for Patients With Chronic Low Back Pain*", uses the acronym MAM as a synonym for MUA, and explains:

> Medication-assisted manipulation incorporates the intravenous administration of sedative and analgesic medication. The rationale for the addition of sedative and analgesic medication to SMT is that it helps to eliminate or reduce pain and muscle spasm that hinder the effective use of traditional manipulation and mobilization. It is perceived that these procedures allow the practitioner to break up joint adhesions and reduce segmental dysfunction to a greater extent than *if medication had not been used* (emphasis added.)

The record submitted by the Board is devoid of any definition of MUA. An appropriate definition appears to be:

> MUA is the manipulation of the spine or other structure during a procedure for which general anesthesia, conscious sedation, or other anesthesia has been

> administered in order to avoid painful sensation and protective guarding or muscle spasm that may result during manipulation, and to alter the physiologic state of muscles or tissues, in order to accomplish change in spinal alignment, the breaking up of intersegmental adhesions, the stretching of soft tissue, or other outcomes sought by the person performing the procedure.

The December 13, 2007 legal opinion provided by the Division of Legal Affairs, Department of Consumer Affairs, misses the mark entirely, perhaps because the request for an opinion, like the proposed regulation, did not describe the nature of the MUA procedure with clarity. The opinion compares a patient medicated by another practitioner with a patient medicated at the request and direction of a chiropractor, and finds no difference:

> Some have put forth the argument that the term "use" should be given its broadest application. For example, if the only way that a chiropractor is able to manipulate a patient is if the patient is sedated, the chiropractor is "using" drugs to accomplish the procedure. This interpretation is not supported by case law and would not be practical in its application. A chiropractor is not authorized to direct a patient to either take or drug or discontinue using a drug. If a patient came in who was using pain medication, the chiropractor would have to decide either not to provide any treatment and later be accused of using drugs because a determination was made that the chiropractor would not have performed the procedure unless the patient was drugged. This interpretation would also lead to an impractical situation for the Board's enforcement program that a patient at the time that a patient received treatment would not have been able to receive that treatment without benefit of drugs. How much pain a patient must tolerate before it is determined that a treatment cannot be performed without using drugs? This would put both the patient and the chiropractor in an untenable situation.
>
> Oftentimes, patients of other healing arts practitioners are medicated in order to ease discomfort related to treatments. For example, many patients are medicated before receiving physical therapy. The medication is necessary not only to ease the pain associated with treatment but also to allow greater benefit to the patient. MUA is no different.

Because the opinion fails to recognize that the MUA patient has been administered drugs in order to achieve physiologic change necessary for performance of the chiropractic procedure, at the chiropractor's instance, it reaches conclusions which cannot survive scrutiny.

The Gordon article in the chiropractic publication *Journal of Manipulative and Physiological Therapeutics* (Attachment "B"), argues that MUA produces good results,

and should be recognized for its virtues. The article cites a procedure code developed under AMA auspices, which can be used in billing third party payors, although the fact of the matter is that very few will pay for MUA procedures except in very limited circumstances. The article asserts that MUA is safe, saying that "historically there have been very few reports of damage from MUA, and most were from medication reaction or the result of the procedure being performed by uncertified, unskilled practitioners." This contention is at least disputable. However, the issue which must determine whether this is a lawful regulation is not the desirability or safety of the procedure, but rather the nature of the procedure. The question is whether or not MUA by definition and in practice is the use of drugs by chiropractors, which is unlawful in California. The Gordon paper makes it clear that use of drugs is integral to the procedure. So do the Kohlbeck and Haldeman articles. This use of drugs is *by the chiropractor*, at the chiropractor's request and direction, and for the chiropractor's own purposes. This would be apparent if the proposed regulation met standards for clarity and necessity. The regulation would then fail because it is inconsistent, and in direct contradiction, measured against statutory authority. The fact that drugs are being used with therapeutic intent is more than irrelevant: it is fatal to the claim that such use is permissible.

Chiropractic manipulation, as it existed in 1922 and ever since in California, has depended upon recognition of patient pain, as a limitation on the stresses being induced. Using drugs eliminates that aspect of the procedure, and that safeguard. Making the anesthesiologist an unwitting accomplice to unlawful practice does not protect the patient, or circumvent the bounds of lawful scope of practice set out in the Chiropractic Initiative Act, as consistently interpreted by California courts and the Attorney General. We ask that these comments, including the Attachments which are included, be added to the record of this proceeding, to demonstrate that the proposed regulation does not comply with Administrative Procedure Act requirements or the Board's authority.

Respectfully submitted,

Michael Champeau MD

Michael W. Champeau, MD
President

Cc: CSA Board of Directors
William E. Barnaby
William E. Barnaby, III

Attachment A

ELSEVIER

The Spine Journal 2 (2002) 288–302

THE SPINE JOURNAL

Technical Report

Medication-assisted Spinal Manipulation

Frank J. Kohlbeck, DC[a], Scott Haldeman, DC, MD, PhD[b,*]

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Received 28 November 2001; accepted 30 April 2002

Abstract

Background context: The acceptance of spinal manipulation as a reasonable method of treating certain patients with spinal pain over the past decade has led to a renewed interest and increased use of these techniques performed in conjunction with commonly used medications and procedures. Manual therapy is increasingly being used in conjunction with anesthetics, sedatives or analgesics as well as local, epidural and intra-articular injections.

Purpose: This report provides a review of the literature and presents a description of current clinical practice methods for the application of the different techniques of medication-assisted spinal manipulation therapy followed by a discussion of the current clinical support and the published indications, contraindications and complications for each of these procedures.

Study design/setting: This technical report integrates a literature review with information gathered through personal interviews, review of medicine-assisted manipulation courses and observations of clinical procedures.

Methods: A PubMed search from 1966 to the present was performed to identify appropriate articles concerning the combination of spinal manipulation therapy with such medical procedures as the use of anesthetic, conscious sedation, local injection of analgesic, anti-inflammatory and proliferant agents and intra-articular injections. Additional articles and information were gathered through review of pertinent references, attendance of various technique specific seminars and communication with experts familiar with these procedures.

Results: Four categories of medication-assisted manipulation were identified: manipulation under general anesthesia or sedation, manipulation under epidural anesthesia with or without epidural steroid injection, manipulation under joint anesthesia/analgesia, and manipulation with injectants, such as steroids or proliferant agents. The literature consists primarily of case reports and case series with two randomized controlled trials and one cohort study.

Conclusions: Medicine-assisted spinal manipulation therapies have a relatively long history of clinical use and have been reported in the literature for over 70 years. However, evidence for the effectiveness of these protocols remains largely anecdotal, based on case series mimicking many other surgical and conservative approaches for the treatment of chronic pain syndromes of musculoskeletal origin. There is, however, sufficient theoretical basis and positive results from case series to warrant further controlled trials on these techniques.

Keywords: Spinal manipulation therapy; Anesthesia; Epidural steroidal injections; Low back pain; Proliferant injections

Introduction

Many proposed options for treatment of patients with intractable spinal pain have been available for decades but have rarely been discussed or thoroughly understood and are seldom the subject of advanced clinical research. Most clinicians will, on occasion, be asked to give an opinion about the value of such treatments, either to patients or to insurance companies. For many procedures, there is little familiarity with the technique and a dearth of literature on which to base opinion or policy. The combination of spinal manipulation with various common medical procedures represents a class of treatment options based largely on empirical evidence related in anecdotal fashion by a small subset of clinicians. The resultant limited published infor-

FDA device/drug status: not applicable.

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mation is often difficult to find and not conducive to definitive statements regarding efficacy of treatment.

Manipulation of the spine under some form of conscious sedation or general anesthesia has been used for at least 70 years [1]. It was a fairly common procedure in many orthopedic practices between 1940 and 1965 [2–6], gradually falling out of favor because of the increasing reliance on improved surgical techniques. There was also a perceived high complication rate during a period when spinal infections, such as tuberculosis, and disc herniation were being better understood. Practitioners who used spinal manipulation without anesthesia during this period considered the manipulation techniques performed under anesthesia to be high force, long lever, high amplitude and nonspecific procedures with the potential for increased complication rates. These practitioners tended to distance themselves from these procedures and to define their techniques as less forceful and more specific than those performed under anesthesia [7]. As orthopedic manipulation went out of favor, a few osteopathic physicians with an interest in manipulation and access to medical facilities began to practice their manipulation techniques in selected patients using anesthesia, sedation and local injections [8,9], but these procedures never gained widespread acceptance. Chiropractors who currently provide the majority of manipulative therapy services in North America [10], on the other hand, were excluded from access to medical institutions and showed minimal interest in medicine-assisted manipulation techniques. A period of marked skepticism in all aspects of spinal manipulation in the 1970s and 1980s also reduced interest in this topic.

In recent years there has been increasing interest and acceptance of spinal manipulation as a treatment modality [11–13]. The experience of some chiropractors working in multidisciplinary settings has led to the recommendation of further establishment of interdisciplinary teams offering a wide range of treatment options, including manipulation therapy [14–16]. Integration of chiropractors into such settings allows chiropractors access to physicians with experience in the use of various forms of medication, including general anesthesia, analgesia, sedatives and various injection techniques. Recent advances in highly titratable and reversible intravenous anesthetics have significantly reduced risks associated with manipulation under anesthesia (MUA), analgesia and sedation [15], which can now be performed in outpatient surgical centers.

This renewed interest has led to numerous, often enthusiastic, claims of success for these procedures with what appears, in certain circumstances, to be indiscriminant use in patients with spinal pain, lack of outcomes data and inconsistent protocols. There are case reports and case series describing the successful use of MUA and other medically assisted manual therapies in patients with a variety of low-back–related conditions, including chronic lumbosacral and sacroiliac strain [1,17], acute and chronic low back pain [18–23], recalcitrant low back pain and lumber radiculopathy [24,25], spinal arthritis [1,3], sciatica [1,26], lumbar disc syndrome [3–6,17,27], myofibrositis with and without disc herniation [3,5], postoperative stiffness [3,28], psoasitis [3], spondylolisthesis [3], cervical radiculopathy, cervical disc herniation, cervicogenic headache syndrome [29], cervical disc syndrome [30], constant intractable pain [31] and failed back surgery syndrome [32]. Favorable responses to medicine-assisted spinal manipulation have also been reported among patients with cervical or thoracic sprain/strain, cervicalgia, brachial neuritis, headache and knee and shoulder injuries [8,33].

This report reviews the literature and current understanding of various techniques of medication-assisted manipulation in an attempt to provide some perspective for the different categories of these therapies. This article should not be perceived as an endorsement or criticism of any of the different techniques, or a recommendation for or against their use. We have reviewed the literature with the aim of informing readers of the current state of the art of medication-assisted spinal manipulation, its rationale, different variations, currently used clinical indications, and the state of published research in support of the procedures.

Rationale

The theoretical justification for the use of manipulation in combination with various medical procedures is that the combined effect may be more successful for symptom alleviation and resolution of pain than the use of the component procedures alone. MUA or sedation is the most prevalent form of medication-assisted spinal manipulation. The rationale for the use of MUA is that anesthesia and analgesia help to eliminate or reduce pain and muscle spasm that hinder the effective use of traditional manipulation or other manual therapies [9,32,33]. Anesthesia, analgesia, or sedation administered systemically or locally is perceived as allowing the practitioner to break up joint adhesions and reduce segmental dysfunction to a greater extent than if anesthesia had not been employed [15,34,35].

Other medicine-assisted manipulation protocols use injections of steroids or proliferant agents with or without the use of anesthesia/analgesia. Steroid injections have been used with manipulation therapy in an attempt to decrease inflammation and thereby allow for greater effectiveness of the manipulation [20,23,24,26]. The injection of proliferant agents is assumed to strengthen supporting ligaments by encouraging collagen growth after manipulation, thereby allowing the effect of the manipulation to be more long lasting [22].

Definitions and techniques

Manipulation under anesthesia

Definition

MUA is the manipulation of the spine while the patient is under general anesthesia or conscious sedation. Anesthesia is employed with the goal of relieving spinal pain, muscle spasm, and protective guarding that may limit other forms of manipulation.

Reported indications

The reported clinical indications for MUA are extensive and for the most part based solely on clinical experience. They include acute or chronic cervical pain, cervicobrachial, cervicocranial, lumbar, pelvic, or lower-extremity syndromes with somatic dysfunctions that have not responded to conservative management [33]. Other authors include patients with major disability or severe musculoskeletal symptoms that may, at least temporarily, be relieved by MUA [9,32].

There is remarkable agreement in the current osteopathic and chiropractic literature concerning the basic indications for MUA [15,29,33,34]. Virtually all recent literature and current MUA guidelines [35–37] endorse a prior course of manipulation therapy without anesthesia. Failure of a 4- to 8-week trial of conservative manipulation therapy to produce significant clinical outcomes is thought to be the primary basis for considering the more aggressive MUA approach. An exception to the requirement for a prior course of conservative manual procedures is represented by patients judged to be candidates for spinal manipulation therapy but who have severe pain, muscle spasm or irritability that prevents the application of manipulation without analgesia or anesthesia.

There is less agreement on the specific indications for MUA or the diagnoses likely to respond. Many proponents of this treatment have developed their own indications. Greenman [33] suggests that the combination of anesthesia with spinal manipulation may be useful for the treatment of chronic vertebral somatic dysfunction and chronic myofibrositis previously unresponsive to conservative care. West et al. [15] have expanded upon these indications, suggesting that MUA may be considered in lieu of spinal surgery, as an interim step in patients who are considering spinal surgery or when the combination of MUA and spinal injection might potentiate the therapeutic benefit of either treatment when used alone. Beckett and Francis [34] add that MUA may be indicated, with caution, when a patient who is a suitable candidate for manual therapy requests the procedure out of apprehension of receiving non–medicine-assisted manipulation.

More expansive lists of indications may be found in the literature [15,35], usually with little explanation as to why the treatment may be effective. These reported indications include patients with bulging, protruded, prolapsed or herniated discs without free fragment who wish to avoid surgery; frozen or fixed articulations from adhesion formation; failed low back surgery; posttraumatic syndrome injuries from acceleration/deceleration mechanisms resulting in painful exacerbations of chronic fixations; chronic recurrent neuromusculoskeletal dysfunction syndromes that are easily exacerbated and neuromusculoskeletal conditions not suited for surgery but that have reached maximum medical improvement with conservative therapies.

Literature review

The English language literature was searched using the PubMed database and such keywords as manipulation, anesthesia, analgesia, injections and sedation. Titles and abstracts of the resulting citations were reviewed in order to identify articles addressing the use of medication as an adjuvant to manipulation therapy. These articles were obtained and their references were reviewed to identify any additional articles. Clinical studies identified are listed in Tables 1 and 2. Table 1 presents a number of articles on MUA. There are no randomized control trials of MUA reported and only one cohort study [38].

The earliest MUA study we identified was published in 1930 by *The Lancet* [1]. In a detailed retrospective study of 113 patients receiving MUA over an 8-year period for low back pain, data were collected using patient questionnaires. Cases were categorized as chronic back strain, sacroiliac strain, lumbosacral strain, spinal arthritis with or without sciatica and neurotic spine. Overall, 56 (75%) of 75 patients with available data improved, and 19 (25%) did not. Patients with chronic back and sacroiliac strain responded best.

In the one cohort study appearing in the literature, Siehl et al [38] tracked 47 patients in a hospital-based orthopedic clinic with low back pain or sciatica and clinical and electromyographic (EMG) signs of nerve root compression that were assigned to receive MUA (21 subjects), nonmanipulative therapy including muscle relaxants, traction, bed rest and other conservative modalities (7 subjects) or immediate surgery (19 subjects). Clinical outcomes were reported at 6 and 12 months according to changes in EMG findings (improved, unchanged or worsened EMG status). Six- and 12-month results revealed that 5 (71%) of the patients receiving conservative treatment remained electromyographically unchanged but demonstrated an improvement in average clinical scores and relative to baseline scores. Two conservative care patients (29%) worsened electromyographically and showed a decrease in average clinical scores from baseline to 6 and 12 months. Patients receiving MUA or surgery demonstrated an improvement in averaged clinical scores at 6 months regardless of change in EMG status. Average clinical scores remained improved at 12 months when compared with the baseline scores. They concluded that MUA would probably result in long-term clinical improvement in the absence of electromyographic evidence of nerve root compression. The authors thought that patients with EMG evidence of nerve root compression were more likely to experience temporary clinical improvement but that this improvement would be transitory and surgical intervention would probably be required at some point.

Five case series appearing in the literature include patients with lumbar disc herniations [2–6]. Wilson and Ilfeld's 1952 work assessed pre- and post-MUA or sedation changes in appearance of the intervertebral disc using fluoroscopy with intraspinal pantopaque [2]. Twelve of 13 patients with a defect interpreted as a herniated intervertebral disc showed no roentgenographic alteration, and a slight increase in the size of the defect was noted in one patient. Three patients experienced temporary relief of back and leg pain, the one patient with slight increase in size of defect ex-

Table 1
Published findings of clinical studies investigating manipulation under anesthesia

Author(s) Date	Study design Number of patients	Condition	Medication	Manual therapy	Outcome
Riches EW 1930	Retrospective review 75	Back pain	Nitrous oxide and ether	Long-lever techniques (forcible flexion and extension of spine; rotatory movement of pelvis)	75% Improved 25% Not improved
Wilson JN and Ilfeld FW 1952	Case series 18	Herniated intervertebral disc	thiopental (n=2) or 1/150 g Scopolamine, 100 mg Meperidine, 3 g secobarbital (n=16)	Long-lever rotary technique	Baseline myelographic studies indicating herniated intervertebral disc—changes observed after SMT: No change in 12 patients Slight increase in defect for 1 patient No defect identified in 5 patients
Siehl D and Bradford W 1952	Case series 87	Low back pain	thiopental	Mobilization of lumber spine and sacroiliac joints	Excellent: 31% Good: 36% Fair: 22% Poor: 11%
Mensor MC 1955	Case series 205	Lumbar intervertebral disc syndrome	IV sodium Pentothal	Long-lever techniques	Excellent: 27% Good: 24% Fair: 16% Immediate failure: 25% Delayed failure: 7%
Siehl D 1963	Case series 666	Back pain	At the discretion of anesthesiologist, usually pentothal or surital	Mobilization	Good: 60% Fair: 30% Poor: 10%
Chrisman DO et al. 1964	Case series with non-MUA "comparison" group 39 cases 22 comparison	Lumbar intervertebral disc syndrome	IV thiopental sodium with succinyl-choline	Long-lever rotatory techniques	Excellent: 28% Good: 26% Fair: 10% Immediate failure: 8% Delayed failure: 28%
Siehl D et al. 1971	Cohort study 47	Lumbar nerve root compression syndrome	General anesthesia	Osteopathic manipulation of lumbar spine	Average clinical scores improved from baseline to 6 and 12 months regardless of improved, unchanged or worsened EMG status
Morey LW 1973	Medical records review 119 (93 low back and 26 cervical spine extremities)	Low back, cervical spine and extremities musculoskeletal disorders	General anesthesia	Mobilization, stretching, long-lever thrusts	Low back / Cervical Spine and extremities Excellent: 26% / 19% Good: 59% / 69% Fair: 13% / 8% No change: 2% / 4%
Krumhansl BR and Nowacek CJ 1986	Case series 171	Intractable spinal pain	thiopental plus inhalant, such as nitrous oxide; fentanyl plus droperidol drip for cervical manipulation	Stretching, long-lever techniques	Pain-based scale: 25% cured 50% much improved 20% better, but 5% failure

(continued)

Table 1
(continued)

Author(s) Date	Study design Number of patients	Condition	Medication	Manual therapy	Outcome
Francis R 1989	Case report	Low back pain	thiopental	Stretching, short-lever adjustment	Resolution of pain
Mennell J 1990	Case series 32	Cervical spine pain	Nitrous oxide or thiopental	Joint-specific therapeutic technique	Outcomes for MUA patients not separated from outcomes for all manipulation patients
Greenman PE 1992	Case report	Painful stiffness of cervical spine	General anesthesia	Mobilization with impulse (high-velocity, low-amplitude thrust technique)	Improved cervical mobility, reduction in pain with no further nausea and vomiting
Alexander GK 1993	Case report	Recurrent HNP with epidural fibrosis	IV thiopental	Stretching and mobilization	Avoidance of surgery
Hughes BL 1993	Case report	Cervical disk syndrome	thiopental	Lower-velocity, high-amplitude thrust	Patient reported improvement
Davis CG et al. 1993	Case reports	Low back pain with sciatica	Nitrous oxide, sodium pentothal, midazolam, propofol, and succinyl-choline	Passive stretching, short-lever thrusts	0–10 Pain scale (10 being worst pain) Patient 1: improvement from 9+ to 2 Patient 2: improvement from 9+ to 3 Both patients had increased lumbar ROM
West DT et al. 1999	Case series 177	Acute and chronic spinal pain disorders	IV midazolam 0.5–1.0 mg/kg propofol	Passive stretching, osseous short-lever arm adjustive technique	ROM: CS 47% improvement LS 83% improvement VAS: CS 62% improvement LS 60% improvement Medication use: 58% reduction
Herzog J 1999	Case report	Cervical disk herniation, Cervical radiculopathy, and associated cervicogenic headache syndrome	methohexital or propofol	Stretching, short-lever low-velocity thrust	Pain scale improvement, 90% improvement of neck and upper back pain, headaches 95% better
Total patients	1,525				

CS = cervical spine; EMG = electromyographic; HNP = herniated nucleus pulposus; IV = intravenous; LS = lumbar spine; MUA = manipulation under anesthesia; ROM = range of motion; VAS = visual analog scale.

Table 2
Published findings of clinical studies investigating various other medicine-assisted manipulation techniques*

Author(s) Date Procedure*	Study design Number of Patients	Condition	Medication	Manual therapy	Outcome
Warr AC et al. 1972 MUEA with ESI	Case series 500	Chronic lumbosciatic syndrome	40 ml of 0.75% lignocaine 80 mg methylprednisolone 25 mg hydrocortisone acetate 300–500 mg propanidid with 0.6 mg IV atropine (2/3 patients) General anesthesia (1/3 patients)	Rotation of spine, bilateral stretching of sciatic nerve	63% success rate (success = complete or near complete relief of all symptoms)
Ben-David B and Raboy M 1994 MUEA with ESI	Case reports 3	Low back pain	8 ml of 1.5% lidocaine 80 mg methylprednisolone	Short-lever technique	80%–100% pain resolution, improved function
Nelson L et al. 1997 MUEA with ESI	Case series 10	Chronic low back pain	10 mg diazepam (oral) 4 cc of 2% lidocaine, 3.5 cc saline 15 mg betamethasone	Short-lever technique	Mean improvement of 25% on "Improvement Scale"
Aspegren DD et al. 1997 MUEA with ESI	Case reports 2	Recalcitrant lumbar radiculopathy	8 cc of 0.25% bupivicaine hydrochloride 2 cc betamethasone	Passive stretching, short-lever technique	Pain reduction, improved ROM
Brown JH 1960 Pressure caudal anesthesia with and without steroid injection	Case series 62	Low back pain with sciatic neuropathy	Morphine, scopolamine 20–30 cc of 1% lidocaine 40 mg. hydrocortisone tertiary-butylacetate Saline	Long-lever technique	Excellent: 53% Good: 31% No therapeutic effect: 16%
Dreyfuss P et al. 1995 MUJA	Case reports 4	Recalcitrant low back pain	Intra-articular injection of corticosteroid and anesthetic	Mobilization and/or short-lever high-velocity, low-amplitude maneuvers	90%–100% pain resolution
Ongley MJ et al. 1987 Proliferant with SMT	RCT 40 cases, 41 controls	Chronic low back pain	IV diazepam Maximum of 60 ml 0.5% lignocaine dextrose 25%, glycerine 25%, phenol 2.5%	Long-lever lumbar roll	Statistically significant differences favoring the experimental over the placebo groups for: Disability Index Visual Analog Scale Pain diagram
Blomberg S et al. 1994 Steroid injections with SMT	RCT 48 cases, 53 controls	Low back pain	triamcinolone	Mobilization, muscle stretching thrust techniques	Statistically significant differences favoring the experimental group over the conventional treatment group for: ROM Standardized physical examination Low back examination and neurologic findings

*Procedures: MUEA, ESI, MUJA, SMT.

ESI = Epidural steroid injection; IV = intravenous; MUEA = Manipulation under epidural anesthesia; MUJA = Manipulation under joint anesthesia/analgesia; RCT = randomized controlled trial; ROM = range of motion; SMT = Spinal manipulation therapy.

perienced transitory worsening of leg and back pain and the remaining patients' symptomatology remained unchanged. In a first study by Siehl and Bradford published the same year [3], 33% of the subjects with herniated discs demonstrated good results (good results defined as a symptom-free patient who returned to normal activity; fair results defined as a patient who demonstrated improvement and returned to relatively normal activity with some residual symptoms, or who temporarily responded but later required surgery or another MUA; poor results defined as little or no improvement or aggravation of symptoms), but those with positive myelographic findings had only temporary relief. Seventy-one percent of the patients with disc herniation in Siehl's follow-up study [5] reported at least temporary improvement. However, 50% eventually required surgery. Of the patients with myofibrositis without herniation, 96% reported successful (good or fair) outcomes. Mensor's study [4] included 205 patients with a clinical diagnosis of intervertebral disc rupture only (no myelography was performed). After an average follow-up of 22.8 months, 51% of the patients reported satisfactory results. In Chrisman et al.'s study [6], 10 of 12 (83%) of the subjects with negative myelograms reported good or excellent results after a 3-year follow-up, whereas 10 of 27 subjects (37%) with positive myelograms reported similar results.

Whereas these earlier studies investigated MUA or sedation for patients with low back pain, three subsequent works included patients with cervical spine–related pain [9,31,39]. In Morey's 1973 review [9] of medical records involving manipulation of the cervical or lumbar spine under anesthesia over a period of 3 years, a total of 119 cases were recorded with 93 involving lumbar spine manipulation and 26 involving manipulation of the cervical spine. Treating physicians reported excellent or good results in 79 lumbar spine cases (85%), fair results in 12 (13%) and no change in 2 cases (2%). Excellent or good results were reported in 23 cervical spine cases (88%), fair in 2 (8%) and no change in 1 patient (4%). In a study published in 1986, Krumhansl and Nowacek [31] reported results of 171 patients receiving MUA of the lumbar and/or cervical spine previously unresponsive to treatment by physicians or physical therapists and to manual therapy without anesthesia. Outcomes were reported as 25% of patients being "cured," 50% as "much improved," 20% as "better, but" and 5% as "failure." Somewhat similar results were reported in a 1990 article by Mennell [39] assessing 100 consecutive cases of patients with pain arising from the cervical spine. Thirty-two of these patients received cervical spine MUA, 51 were manipulated without anesthesia and 17 did not receive any spinal manipulation therapy. Data specific to the MUA cases were not presented, but overall results of patients receiving spinal manipulation with or without use of anesthesia reveal 25 patients (30%) with symptoms cured, 29 (35%) with marked improvement, 24 (29%) with moderate improvement and no change in 5 (6%).

A number of case reports can be found in the literature detailing successful application of MUA in patients with low back and leg pain [17,28,30,32], painful stiffness of the cervical spine with intractable nausea [33], and cervical disc herniation, radiculopathy and associated cervicogenic headache [29]. Resolution of symptoms or marked improvement was reported in these case reports of patients previously unresponsive to prior surgeries or conservative care consisting of spinal manipulation without anesthesia, physical therapy modalities, traction, or anti-inflammatory and pain medications.

A recent case series by West et al. [15] presents the results of 168 patients with acute and chronic spinal pain disorders who completed a series of MUA treatments. Average visual analog scale (VAS) scores improved 4.6 points (on a scale of 0 to 10 points) 6 months after MUA for patients with cervical pain. Patients with lumbar pain improved an average of 4.31 points over the same period. Decrease in time out of work and less use of prescription pain mediation were also reported for both groups.

Protocol

Most protocols recommending MUA do not consider this a stand-alone treatment. These protocols require a prior trial of conservative management followed by mobilization and manipulation techniques with the use of general anesthesia and a course of post-MUA rehabilitation involving continued stretching and strengthening exercises and palliative postprocedure pain management. Early manipulation techniques employed typically by osteopaths and orthopedic practitioners favored long-lever, more general maneuvers. Current procedures more commonly use specific, short-lever, high velocity low amplitude thrusts characteristic of chiropractic and modern osteopathic adjustive techniques in addition to mobilization.

A typical MUA procedure involves placing the patient in a twilight anesthesia by a board-certified anesthesiologist while the clinician with the aid of a skilled assistant provides specific mobilization and manipulation techniques to the affected joints and spinal regions. Patients are instructed to abstain from food or drink for 8 to 12 hours before the procedure. Intravenous administration of propofol has been the most commonly recommended anesthetic agent, although many practitioners also use midazolam to provide amnesia. Before the procedure the patient is connected to a cardiac monitor, blood pressure cuff and oximeter. A small intravenous catheter is inserted in the patient's arm. The manipulation and mobilization take approximately 10 to 20 minutes. Although both high- and low-velocity thrusts are employed, the recommended force of the manipulation is described as much less and more cautious than when anesthesia is not used [15,30,32,35,37]. High-velocity thrusts are employed to break up intersegmental adhesions, whereas low-velocity mobilization is used to passively stretch soft tissue. Once the procedure is completed, the patient is transferred to a recovery room and monitored by the attending anesthesiologist until vital signs are stable. An attending nurse should continue monitoring the patient, who may be offered oral fluids and a light snack once the fluids are well tolerated.

When fluids and food are tolerated and the vital signs remain stable, the patient may be discharged to a responsible adult escort for transportation away from the facility [40].

The specific manipulative and mobilization procedures depend on each patient and the area of pain and/or dysfunction. All range of motion mobilizations to any region of the spine and extremities are performed with full knowledge of both active and passive end range exhibited by the patient in a fully conscious state. Current guidelines recommend the presence of a primary physician and assisting physician who have both undergone adequate training in MUA procedures. An assistant is necessary to position and stabilize the sedated patient.

Current protocols suggest that patient response to the first MUA procedure should determine the need, if any, for further procedures [40]. These guidelines suggest the recovery of at least 80% normal function (as determined for the individual patient by prior examination and history) indicates no need for serial procedures. Recovery of less than 70% function but accompanied by some measurable improvement may indicate the need for a second MUA procedure. Continuing improvement that fails to reach the 80% threshold may indicate the need for a third MUA procedure [40]. Attempts to establish less arbitrary criteria are quashed by the lack of studies with methodology appropriate for determining efficacy and dose response.

For cervical complaints, passive stretching of the soft tissues is accomplished in separate maneuvers emphasizing various range of motion movements, such as axial traction, forward flexion, lateral flexion and rotation of the cervical spine while the patient is in a supine position (Fig. 1). After isolating the segments to be manipulated, a controlled manipulative thrust is directed to the involved joints. The cervical spine is placed in slight lateral flexion with minimal rotation, and the thrust employed is typically much lighter than used with fully conscious patients (Fig. 2).

If the thoracic spine is to be treated, the patient remains supine with the arms crossed over the chest. Typically, the practitioner isolates the segments by rolling the patient to one side just enough to place a loose fist that acts as a fulcrum under the thoracic spine. The patient is returned to a supine position, and the clinician places a hand on the patient's crossed arms. A slight anterior-to-posterior thrust is applied, and the procedure is repeated until all segments identified by prior patient history and physical examination have been addressed (Fig. 3).

A number of stretches are applied to the lumbar spine and pelvis for patients with complaints involving the low back. Straight leg raise mobilization with dorsiflexion of the foot is applied, as well as a variety of knee-to-chest maneuvers (Fig. 4). Stretches are applied bilaterally. Traction of the leg with the hip in neutral, internal and external rotation is often applied. Mobilization of the hips and pelvic girdle may also be accomplished by flexing the patient's lower extremity at the knee and placing the foot on the table around the level of the patient's contralateral inner thigh (Fabere-Patrick maneuver) followed by external and internal rotation at the hip. Traction of the lumbar spine is often applied by bringing the patient's knees to the chest while contacting the lumbar and/or sacral spine. The patient is rolled from the supine to a side-lying position with the lower extremity in flexion. Additional mobilization may be applied before manipulation of the lumbar spine and sacroiliac joints (Fig. 5). The patient is returned to a supine position at the completion of all MUA procedures and usually transported to a recovery room for observation until ready for discharge from the facility.

Fig. 1. The practitioner (right) administers axial traction to the cervical spine, cupping the patient's posterior skull with his left hand while he cradles the patient's jaw with his right hand. The first assistant (left) stabilizes the patient with bilateral shoulder/upper trapezius contacts. The anesthesiologist steps aside to allow the clinician access to the patient's head and neck area during cervical spine mobilization and manipulation. During all other maneuvers, the anesthesiologist monitors the patient from the head of the table.

Virtually all current guidelines and authors describing MUA protocols recommend a 2- to 6-week period of post-MUA rehabilitation therapy. Continued mobilization and manipulation is recommended, as well as appropriate application

Fig. 2. The clinician (right) administers cervical spine manipulation using a specific low-amplitude, short-lever technique with minimal thrusting force. The clinician's lower (left) hand and arm are used solely to stabilize the patient's head and neck while the upper (right) hand delivers a controlled thrust. The first assistant stabilizes the patient's body by holding the shoulders.

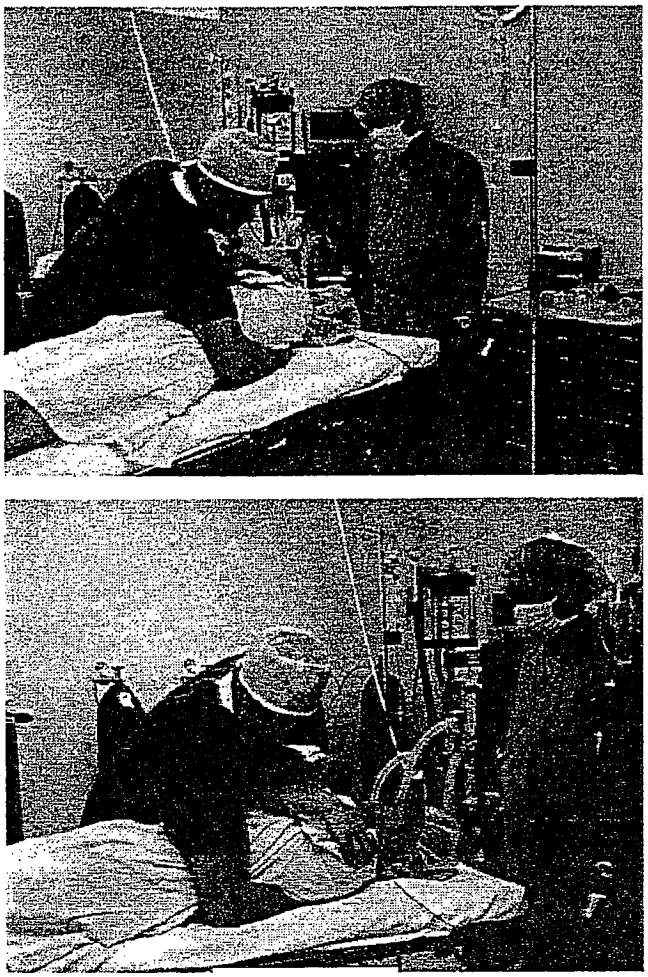

Fig. 3. (Top) The clinician positions his hand under the patient's thoracic spine to act as a fulcrum. (Bottom) The patient is returned to a supine position with arms crossed over the chest and the clinician applies a quick anterior to posterior thrust using a contact with his left hand (lower photograph).

of physical therapy modalities. Transition from passive stretches and modalities to active exercise and muscle strengthening is stressed during the course of rehabilitation.

Reported complications

In theory, complications could occur as the result of the anesthesia or the manipulative force. Complications reported in the literature as being associated with MUA include cauda equina syndrome [41,42], paralysis [42], vertebral pedicle fracture [41] and dens fracture with C1–C2 dislocation [43]. These complications, however, were reported in the early orthopedic literature that were surveys not specific to MUA and assessing techniques employing long lever manipulation. Table 3 lists adverse reactions reported by the authors of studies specifically investigating MUA. Use of long-lever techniques applied under general anesthesia resulted in few complications reported in the case series. Riches [1] and Chrisman et al. [6] reported exacerbation of symptoms in 1 of 75 and 5 of 39 patients, respectively. The five patients with exacerbated symptoms in Chrisman et al.'s study reported in 1964 consisted of patients with immediate complaints of increased lumbosacral pain and muscle tightness, although improvement in leg pain was noted. These patients were then treated with plaster body jackets. A table appearing in Chrisman et al.'s article appears to indicate that three of these five patients were rated as good or excellent 6 to 8 weeks after manipulation with one patient classified as an immediate failure and one classified as a delayed failure [6]. Krumhansl and Nowacek [31] reported two cases of intractable respiratory distress of 171 patients, which resolved after a return to the operative suite. They also documented "pain paralysis" in an additional two patients who experi-

Fig. 4. A straight leg raise stretch is applied by the clinician while the first assistant stabilizes the contralateral leg. All mobilization and manipulation are applied with an awareness of the preprocedure range of motion of the fully conscious patient. Maneuvers are typically performed bilaterally.

Fig. 5. Manipulation of the lumbar spine and sacroiliac joint is accomplished by placing the patient in a side-lying posture. The first assistant (left) helps to stabilize the patient while the clinician contacts specific sacral and/or lumbar segments to deliver the adjustive thrust. The clinician is positioned to ensure patient safety. The thrust is delivered only through the hand that is contacting the patient's spine.

enced transitory inability to move their lower extremities because of severe pain in the sacroiliac joint for a period of 1 week or less. Neither patient demonstrated sensory or neurological damage, and both recovered completely within 10 days [31]. Wilson and Ilfeld [2] indicated a slight increase in the size of defect demonstrated by myelography (interpreted as being the result of herniation of the intervertabral disc) after manipulation in 1 of 18 patients. We have been unable to find any report of complications using more modern osteopathic and chiropractic techniques or as a result of the use of anesthesia. Overall, the authors of the 17 MUA articles from 1930 to the present reviewed in this article report adverse reactions or complications in a total of 11 (0.7%) of 1,525 patients.

Manipulation under joint anesthesia/analgesia

Definition

Manipulation under joint anesthesia/analgesia (MUJA) is the combination of fluoroscopically guided intra-articular injections of anesthetic and corticosteroid agents and subsequent manipulations of the injected joints [25,44].

Reported indications

MUJA combines manipulation therapy with fluoroscopically guided intra-articular injections of anesthetic and corticosteroid agents. Dreyfuss et al. [25] suggest the use of MUJA for patients with recalcitrant spinal synovial joint–mediated pain. These authors think that the anesthetic component of MUJA provides the following potential clinical benefits: 1) a single anesthetic block of the zygapophyseal joint or sacroiliac joint and its capsule that would block the pain-mediated nerve supply may tentatively confirm or deny the working diagnosis of z-joint– or sacroiliac joint–mediated pain, and 2) the anesthetic block provides a brief window of opportunity for spinal manipulation therapy delivery while the patient is relaxed and in a relatively pain free state. The use of corticosteroids with MUJA has been proposed as a means of providing two additional benefits: 1) the corticosteroid agent alone may provide long-lasting therapeutic effect by reducing inflammation, and 2) the corticosteroid may extend the window of opportunity for spinal manipulation therapy beyond the anesthetic effects [25].

Literature review

There are no controlled clinical trials or large case series describing the outcome using these techniques (Table 2). Dreyfuss et al. [25] present four cases where the MUJA procedure was performed. These patients are described as having lumbar zygapophyseal joint– and/or sacroiliac joint–mediated pain diagnosed by fluoroscopically guided, contrast-enhanced, intra-articular anesthetic injections. Before undergoing MUJA, each of the four patients had an extensive treatment history, including care provided by family doctors, physiatrists, physical therapists, chiropractors and/or neurologists. Improvement in pain appears to be the main outcome measure with each patient experiencing 80% to 100% improvement, which was sustained for a follow-up period of 4 to 6 months.

Protocol

Fluoroscopically guided joint injections of anesthetic and/or corticosteroid agents are recommended by the proponents of these procedures to ensure specificity of delivery. A radio-opaque contrast agent is used to confirm needle placement and delivery of injected material into the joint or into the tissues surrounding the pain-mediated nerve supply. Anesthetic agents, such as lignocaine (1.5cc of 2% solution) with or without corticosteroids (eg, 0.5 cc celestone soluspan), are injected directly into the joint. Manipulation is applied only if the injection establishes a diagnosis of predominant joint-mediated pain. Michaelsen and Dreyfuss [44] state that a reduction in pain limited to 50% indicates additional pain generators other than the joints injected. Reduction in 90% to 100% of pain after the injection of anesthetic agent is considered a strong indication that the injected sites are the anatomic structures responsible for the patient's pain.

Manipulative procedures commonly used with this procedure may be short-lever, high-velocity, low-amplitude manual techniques or less forceful spinal joint mobilization therapy. Six to eight sessions of spinal manipulation therapy are commonly recommended within the first 10 to 12 days after the intra-articular injections of anesthetic and corticosteroid. This is then followed by the introduction of such active therapies as muscle stretching exercises, aerobic and general conditioning and strengthening exercises, which presumably were not well tolerated before the injection.

Reported complications

This technique is relatively new and there are no reported complications. Theoretically the complications associated with manipulation or with the intra-articular injection of anesthetic should be considered. Dreyfuss et al. [25] reported no complications with MUJA occurring in their four patients, but there are no large case series to determine rate of complications.

Manipulation under epidural anesthesia

Definition

The use of an epidural segmental anesthetic often with simultaneous epidural steroid injection (ESI) followed by spinal manipulation therapy has been referred to as manipulation under epidural anesthesia (MUEA) [24].

Reported indications

Ben-David and Raboy [20] suggest several benefits of MUEA relative to MUA: MUEA is a less costly alternative to MUA, patients may be more receptive to the use of local anesthetic rather than general anesthesia and the use of steroid injections during the procedure may reduce inflammation secondary to the manual treatment and inhibit reformation of fibrosis and adhesions. Clinical indications proposed for MUEA include chronic mechanical low back pain [20,21], lumbosciatic pain [18,26] and recalcitrant lumbar radiculopathy [24].

Table 3
Reported complications of manipulation under anesthesia by study

Author(s) Date	Reported complications	COMPLICATION RATE* complications: patients (%)
Riches EW 1930	One patient of 75 reported worse back pain as a result of manipulation. Upon examination, she displayed diffuse tenderness of entire back, but good flexibility despite radiological evidence of osteoarthritic lipping of the lumbar vertebral bodies.	1:75 (1.3)
Wilson JN and Ilfeld FW 1952	One of 13 patients with myelographic evidence of herniated intervertebral disc showed a slight increase in the defect immediately after manipulation with anesthesia or analgesia. This patient also noted increased pain in his back and leg, which subsided in 2 days.	1:13 (7.7)
Siehl D and Bradford W 1952	No reported complications in a series of 100 low back manipulations under general anesthesia involving 87 different patients.	0:87 (0)
Mensor MC 1955	No aggravation of symptoms by manipulation for the 205 patients in this study. No occurrence of motor weakness, paralysis or complication of the bladder or rectal sphincter.	0:205 (0)
Siehl D 1963	No reported complications in a series of 723 cases of manipulation under anesthesia performed on 666 separate patients (including the 87 patients contained in Siehl and Bradford's 1952 report).	0:666 (0)
Chrisman DO et al. 1964	Five of 39 patients complained of increased lumbosacral pain and muscle tightness immediately after manipulation under anesthesia.	5:39 (13)
Siehl D et al. 1971	No reported complications in 21 patients receiving manipulation under anesthesia.	0:21 (0)
Morey LW 1973	No reported complications in 119 patients undergoing manipulation under anesthesia, 93 receiving lumbar spine manipulation and 26 receiving manipulation of the cervical spine.	0:119 (0)
Krumhansl BR and Nowacek CJ 1986	Four patients of 171 receiving manipulation of the lumbar and/or cervical spine under anesthesia experienced complications. Two lumbar spine patients were returned to the operative suite because of intractable respiratory distress, which was resolved with Valium. Two patients experienced severe pain in the sacroiliac joints, which prevented leg movement for 3 to 7 days. Both patients recovered completely within 10 days.	4:171 (2.3)
Francis R 1989	Case report with full resolution of symptoms and 12-month follow-up. Author states similar results in over 20 MUAs performed but offers no details.	0:1
Mennell J 1990	No reported complications in this study of 100 consecutive cases with pain arising from cervical spine. Thirty-two patients received MUA of the cervical spine.	0:32 (0)
Greenman PE 1992	Case report with full resolution of presenting symptoms (painful stiffness of cervical spine, intractable nausea) lasting for at least the following 18 months.	0:1
Alexander GK 1993	Case report of MUA for low back pain with satisfactory results.	0:1
Hughes, BL 1993	Case report of MUA series for patient with restricted cervical spine motion, pain and paresthesia after a motorcycle accident. Resolution of symptoms reported.	0:1
Davis CG et al. 1993	Two case reports of MUA for chronic, severe low back pain and sciatica that failed to respond to numerous surgeries. Marked improvement in pain and function with decreased dependence on medication use was reported for both patients.	0:2
West DT et al. 1999	No complications reported in a case series of 177 patients receiving MUA.	0:177 (0)
Herzog J 1999	Case report of MUA for patient with cervical disc herniation, cervical radiculopathy and cervicogenic headache. Patient reported 95% improvement in overall condition.	0:1
Total patients*		11:1,525 (0.7)

*Total represents unique patients taking into account the duplication of the 87 patients appearing in Siehl and Bradford's 1952 study and follow-up study by Siehl in 1963.

MUA = manipulation under anesthesia.

Literature review

Several case reports and case series describe the use of MUEA with or without ESI for the treatment of recalcitrant lumbar radiculopathy [24], severe low back pain with degenerative changes [20], chronic mechanical low back pain [21] and chronic lumbosciatic syndrome [18,26] (Table 2).

We were able to find two case reports of MUEA with ESI [20,24] documenting the use of this combination therapy. Aspegen et al. [24] reported the use of MUEA with ESI for the treatment of one case of L5 intervertebral disc syndrome with peridural scar formation and one case of L4 intervertebral disc syndrome with radiculopathy. Both patients received conventional care (oral medications, physical therapy, spinal manipulation therapy) before undergoing MUEA with ESI. Improvement was reported clinically and on VAS, Oswestry Disability Index and pain drawings.

Ben-David and Raboy [20] provide a further three cases of MUEA with ESI. After failure of manipulation therapy alone in two patients and of ESI alone in the third patient, all three patients reported dramatic immediate improvement when both treatments were administered together. The effect was transient, but the authors report that subsequent response to clinical management with manipulation therapy appeared enhanced.

Three case series discuss the use of ESI and local anesthesia with manipulation for chronic mechanical low back pain [21] and chronic lumbosciatic syndrome [18,26]. Nelson et al. [21] performed a retrospective analysis on 10 of 17 cases of patients with chronic low back pain experiencing suboptimal (less than 50% improvement) response to conventional care. The main outcome measure used was an "improvement scale" consisting of a line marked in 10% increments from 0% (no improvement) to 100%. On average, the patients reported a 25% improvement with manipulation combined with ESI over and above any improvement reported after conventional care. Warr et al. [26] followed 500 patients who had not responded to conservative care. Manipulation with ESI resulted in a success rate of 63% (success defined as complete or near complete relief of all symptoms, lack of recurrence within the follow-up period and no requirement of further treatment) with patients reporting immediate favorable results extending for at least 6 months. The remaining 37% of patients experienced temporary relief that was attributed to the effects of the steroid injection. Brown [18] reported 62 cases of patients experiencing low back pain after trauma. Twenty-one patients had a prior history of surgery, and all patients had undergone long periods of conservative therapy, including bed rest, traction, physical therapy and back supports, which achieved transient relief of pain. Manipulation after pressure caudal anesthesia was administered in all patients, with 20 patients also receiving steroid injections. The authors report excellent results in 53% of patients, good results in 31% and no appreciable benefit in 16% (excellent results defined as complete and persistent relief of sciatic root pain for a minimum of 3 months, good results defined as either transitory elimination or striking reduction of persistent root pain after each procedure).

Protocol

Manipulation under epidural anesthesia with ESI usually involves a fluoroscopically guided epidural analgesia and steroid injection (typically, lidocaine and methylprednisone) followed within 15 to 30 minutes by the manual procedures outlined in the above MUA section. Lumbar stretching followed by spinal manipulation is the most common approach. Unlike MUA, the patient is able to cooperate during the procedure. It is therefore not considered imperative that an assistant be available to aid in positioning the patient during the manipulation, as is the case of MUA. Postprocedure treatments typically consist of stretching, standard manipulation therapy and therapeutic modalities as indicated.

Reported complications

Warr et al. [26] report no serious complications in 500 patients receiving manipulation with epidural injections, although thecal puncture occurred in 7 cases. The procedure was abandoned, and the epidural injections were performed successfully 1 week later in each of these cases. The case series by Brown [18], where manipulation was applied after pressure caudal anesthesia, describes four patients in which a mild transitory (lasting a few seconds) tetanic convulsive episode developed after 30 to 40 cc of saline had been injected. None of the episodes were recognized by the patients or produced sequelae. In each case discontinuation of injection allowed for completion of the manipulation.

Manipulation with proliferant or steroid injection

Definition

Other medicine-assisted manipulation therapies discussed in the literature include manipulation combined with cortisone injections into paraspinal tissues and proliferant injections. Blomberg et al. [23] discussed the use of cortisone injections into the paracoccygeal structures and into the insertion of the piriformis muscle on the greater trochanter as an essential component of a pragmatic approach to low back pain, which also includes the use of manipulation, specific mobilization, muscle stretching, home exercises and traction. The regimen proposed by Ongley et al. [22] consists of injection of a proliferant solution into sacroiliac and paraspinal ligaments considered to be of value when used in conjunction with manipulation, local anesthesia and repeated flexion exercises.

Reported indications

Both of these regimens were proposed as new approaches to the treatment of low back pain, and both use injections as one component of manual therapy protocols that involve mobilization and manipulation. Neither of these authors have been very specific in their indications with the populations studied consisting of acute and subacute subjects with low back pain [23] or patients with chronic low back pain [22].

Literature review

Blomberg et al. [23,45,46] studied manual therapy with steroid injections in a multicenter trial (Table 2). Fifty-three patients with acute or subacute low back pain receiving conventional treatment were compared with 48 patients receiving experimental treatment, which included manual therapy and cortisone injections. Results revealed a reduction in objective findings of low back pain on physical examination, decreased pain, decreased drug consumption, decrease in sick leave and disability rating and an increase in quality of life.

Ongley et al. [22] randomized 81 patients with chronic low back pain into two treatment groups. One group of 40 received manipulation and injections of local anesthesia (dilute lignocaine) and a proliferant solution containing dextrose-glycerine-phenol. The control group of 41 patients re-

ceived treatment with less extensive use of initial local anesthesia and manipulation and the substitution of saline for the proliferant solution. Using modified versions of the Roland-Morris disability index, Waddell's chronic disability index and a visual analog scale to measure outcomes, the authors reported greater improvement in disability and pain scores for the experimental group at follow-ups of 1, 3 and 6 months. In the experimental group, 35 of 40 patients (88%) reported greater than 50% improvement in disability scores as compared with 16 of 41 patients (39%) in the control group. Mean disability scores at 6 months were 3.41 (of a possible 33 with 33 representing most disability) in the experimental group and 8.29 in the control group ($p<.001$). Differences in pain scores (measured using a visual analogue scale with a maximum of 7.5) at 6 months were also statistically significant ($p<.001$) between the experimental group (VAS=1.5) and the control group (VAS=3.08)

Protocol

The protocol described by Blomberg et al. [23,45,46] combined manipulation, mobilization, muscle stretching, home exercises, autotraction and cortisone injections. All patients received manipulation with thrust techniques or specific mobilization of the low back and sacroiliac joints. Autotraction was part of the protocol for a small subset of patients. Patients were treated with these manual therapies for 1 to 2 weeks before the procedure. Patients nonresponsive to treatment were further assessed through per rectum palpation of paracoccygeal structures or palpation of the piriformis insertion on the greater trochanter. Steroid injections (triamcinolone) and injection of local anesthetics were administered at these sites. Follow-up care by physicians and therapists were provided for patients who experienced recurrence of pain with the average number of visits being 3.5 and 2.8 times, respectively.

Ongley et al. [22] provide a detailed description of their 6-week treatment protocol that combines a single administration of long-lever manipulation of the lumbar and sacroiliac areas with injection of local anesthetic and proliferant solution. On the first visit, all patients received 10 mg diazepam intravenously for relaxation and amnesia. Through a single insertion point at the L5 spinous process, a rigid needle was used to inject a maximum of 10 ml of 0.5% lignocaine at the tip of the L4 and L5 spinous processes and associated ligaments; the attachment of the ligamentum flavum along the borders of the L4 and L5 laminae; apophyseal joint capsules at L4–L5 and L5–S1; the attachment of the iliolumbar ligament on the transverse processes of L4 and L5; the attachment of the iliolumbar ligament and dorsolumbar fascia to the iliac crest; the attachments of short and long fibers of the posterior sacroiliac ligaments and the sacral and iliac attachments of the interosseous sacroiliac ligaments. An injection of 50 mg triamcinolone in 10 ml 0.5% lignocaine (proliferant solution) was administered into the origin of the gluteus medius. These injections were followed by manipulation of the lumbar and sacroiliac areas with an assistant immobilizing the patient's thorax and the therapist using the thigh as a lever to apply rotary and flexion forces. Injection of the proliferant solution was repeated on a second visit, and flexion exercises were introduced, which consisted of repeated active forward flexion of the lumbar region in a standing or seated position. These first two visits were followed by repeated weekly injections of proliferant solution for the duration of 6 weeks and continued flexion exercises.

Reported complications

Ongley et al. [22] reported patient complaints of pain and stiffness for 12 to 24 hours after each injection for both groups of patients. Two patients in the experimental group and one patient in the control group experienced increased menstrual flow. Two patients in the experimental group had postmenopausal spotting 4 weeks after the start of treatment, and one patient in the control group withdrew after the injection on day 2 because of a severe headache and cough.

Contraindications for medicine-assisted spinal manipulation

As with any procedure, suggested contraindications are categorized as absolute and relative and are generally based on common sense. Any contraindication to spinal manipulation therapy without the use of adjuvant medication should be considered a contraindication to medicine-assisted spinal manipulation. In addition, any medical condition that precludes the use of analgesia, anesthesia or injection of corticosteroids and/or proliferant solution would prevent the use of these combination therapies.

Suggested absolute contraindications include any form of primary or secondary malignant process involving the spinal cord or vertebral structures. Joint hypermobility or instability, acute inflammatory conditions, bone/joint infection, acute bone fracture in the area to be treated, progressive neurological deficits and the presence of large aortic aneurysms represent absolute contraindications [15,33–35]. Relative contraindications include osteoporosis, herniated nucleus pulposus, prior spinal surgery to treatment area and other relative contraindications of spinal manipulation therapy [17,33,34]. These conditions may warrant a more careful administration or modification of the manipulation technique.

Additional risks are introduced by the use of an anesthetic agent. Anesthesia and sedation reduce the patient's ability to provide immediate feedback of experienced pain or to guard against overzealous administration of manual techniques. Patient–clinician communication is preserved throughout procedures using local anesthetics, as with the MUJA and MUEA protocols. Of special concern when combining anesthesia or conscious sedation with a procedure involving numerous potential changes of patient positioning during mobilization and manipulation maneuvers is vigilant monitoring and preservation of the patient's airway.

Discussion

Review of the literature on medication-assisted spinal manipulation leaves one in the same state of confusion and skepticism aroused by similar reviews of many other treatment protocols for spinal pain, including many surgical and injection techniques. There is ample enthusiasm by proponents, reasonable theory to support the consideration of the technique, a number of case series with very few controlled clinical trials and claims that a substantial portion of patients receiving the treatment report improvement of their symptoms and are satisfied with their care. In addition, as with surgical procedures, there is a proliferation of new methods of combining medication with manipulation that makes future studies more difficult and serves to confuse patients and clinicians trying to get beyond the personal experiences and techniques advocated by a single provider or small group of providers.

The suggestion that combining commonly applied treatment approaches may be more beneficial than a single approach appears intuitively reasonable. The difficulty with this thinking is that many of the treatments used as components of these combination procedures have yet to be established as valuable treatment modalities in their own right for the conditions being treated. The use of spinal manipulation in patients with uncomplicated low back and neck pain is growing [47] and most reviews of randomized trials of spinal manipulation suggest that current research supports the role of manipulation [11,48,49]. The problem arises when medication-assisted manipulation is recommended for very specific conditions, such as disc herniation, facet syndrome, ligamentous laxity, and so forth. Very few controlled trials on the effectiveness of manipulation have selected patients with these specific diagnoses. Similarly, the controlled clinical trials that investigate the injection of local anesthestics, epidural injections and sclerosing agents are either scarce or inconclusive. For example, a recent systematic review of conservative treatments for acute and chronic nonspecific low back pain included an assessment of epidural injections [49]. One randomized controlled trial investigating the use of ESIs for acute low back pain was found, indicating limited evidence for the effectiveness of ESIs for acute low back pain with nerve root pain and radicular neurologic deficit. Six randomized controlled trials identified in van Tulder et al.'s systematic review [49] suggested moderate evidence supporting the short-term effectiveness of ESIs as compared with placebo for chronic low back pain but no evidence regarding increased effectiveness of ESIs over injections of local anesthetic or muscle relaxant.

The use of manipulation under sedation or anesthesia suggests that there is a dose response to manipulation. This assumes that if mobility associated with manipulation is beneficial, then greater mobility anticipated from manipulation and mobilization during muscle relaxation should be more beneficial. This basic hypothesis has yet to be studied. It has also yet to be shown that medicine-assisted manipulation techniques are any more effective than manipulation by itself.

Although medicine-assisted spinal manipulation therapies have a relatively long history of clinical use and have been reported in the literature for over 70 years, evidence for the effectiveness of these protocols remains largely anecdotal. Lack of strong clinical trials has not diminished the growing utilization of these procedures. Although we have not been able to find reliable data on utilization, there is an obvious greater interest in these therapies. Currently, one surgical center in California claims that approximately 50 MUA procedures are being performed there every month. Rigorous studies evaluating patient selection, risks and benefits of these therapeutic approaches are needed. The long history of this treatment approach and the encouraging case series are reason enough to spend resources to conduct controlled clinical trials or at least comparative cohort studies. Without such studies, it is not possible to reach any definitive conclusion as to the benefits or risks of these procedures.

Until we have greater understanding of the procedure and a substantial body of research on which to base any discussion of medication-assisted manipulation, clinicians and payers will have to base opinions on their personal requirements and insist on research for any procedure offered patients with spinal pain. If a clinician recommends or offers, and a payer reimburses, surgery, injections, epidurals and certain physical therapy approaches to patients without requiring substantial proof of effectiveness and safety, then it would be difficult to deny the use of medication-assisted manipulation or fail to reimburse for it. If on the other hand a clinician or payer rejects all surgery that does not have a body of controlled clinical trials supporting its use and refuses to offer patients or pay for most injection and physical therapy procedures that have limited or no research support, then it would be reasonable to reject medication-assisted manipulation until such research is carried out and published. It would seem unreasonable, however, to hold medication-assisted manipulation to a higher standard of scientific rigor than that required of other treatment approaches. Clearly, it is more desirable to offer and pay for treatment with an established body of research support and clear understanding of its indications, contraindications and risks. The hope is that this will be forthcoming in the near future for the various forms of medication-assisted manipulation.

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Attachment B

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COMMENTARY

An Evaluation of the Experimental and Investigational Status and Clinical Validity of Manipulation of Patients Under Anesthesia: A Contemporary Opinion

For more than 60 years, manipulation of patients under anesthesia (MUA) has been performed by osteopathic physicians, orthopedic surgeons, and, in the past 10 years, by chiropractic physicians. More than 40 articles and publications have been written on this subject in the peer-reviewed literature and clinically documented patient-outcome reviews. Part of the attraction of performing MUA is that since it was first used in the osteopathic profession,[1] results have been remarkable for properly selected cases.[2] These results have been duplicated over the years and have continuously improved. The results achieved today are similar to those achieved by Siehl,[3] Morey,[4] Clyborne,[5] and Krumhansl[6] who performed MUA in the earlier part of the 20th century. If anything has changed, it is in the enhancement of techniques that were used by the early MUA practitioners. As modern manual therapists began to investigate MUA and add to these earlier techniques,[7-10] they found that modifying and changing some parts of the procedures made an already good technique even better.

However, within the past 4 years, as the procedure has become more widely used, debate has been waged over the efficacy of MUA; those who question the validity of MUA have drawn on outdated literature[5,11] to create doubt about the clinical validity and the therapeutic value of MUA.

I believe there are several concerns that need to be addressed to justify the use of MUA:

1. Has MUA been practiced enough and with enough reliability to be evaluated as a form of therapy that achieves similar results when used with recommended types of conditions that have been shown historically to respond favorably to MUA?
2. Is MUA an experimental procedure? Does the definition for "an experimental procedure" apply to this procedure?
3. How safe and effective is MUA, and has MUA historically been shown to be safe and effective?
4. What is the current relationship between acute and chronic neuromusculoskeletal spinal pain and results obtained with MUA?
5. Is a controlled or double-blind study possible with the MUA technique as it is being done throughout the United States? If not, are the outcomes being achieved today any less significant?

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Has MUA been practiced enough and with enough reliability to be evaluated as a form of therapy that achieves similar results when used with recommended types of conditions that have been shown over the years to respond favorably to MUA?

Because MUA has its own Current Procedural Terminology (CPT) code in the American Medical Association (AMA) CPT code book of reimbursable procedures,[12] it must have been proven over the years to have both reliability and clinical validity. The CPT codebook, written by a medical committee that researches procedures for reimbursement by third party payors, does not recommend unproven procedures. The CPT code book for 2000 specifically states, "Inclusion of a descriptor and its associated specific 5-digit identifying code number in CPT is generally based upon the procedure being consistent with contemporary medical practice and being performed by many physicians in clinical practice in multiple locations."[12]

In the AMA's Current Procedural Terminology,[12] the following statement is also made regarding the panel and the process for accepting a code: "The CPT Editorial Panel is responsible for maintaining CPT. This panel is authorized to revise, update, or modify CPT. The panel is made up of 16 physicians, 11 nominated by the AMA and one each from the Blue Cross and Blue Shield Hospital Association, and the co-chairman of the HCPAC (Health Care Professional Advisory Committee). AMA's Board of Trustees appoints the Panel members." In addition to the Advisory Committee opinions, current medical periodicals and textbooks are used to provide up-to-date information about the procedure or service. Further data are also obtained about the efficacy and clinical utility of procedures from other sources, such as the AMA's Diagnostic and Therapeutic Technology Assessment program and various other technology assessment panels.

The CPT code book is used by third party payors as a reliable source for recognition of reputable procedures recognized by the AMA. Because spinal MUA has its own CPT code (22505), it is recognized by the AMA as a valid procedure. The CPT code book recognizes CPT code 22505 as "spinal manipulation under anesthesia of any area."[12] MUA has met the requirements for inclusion in the CPT code of reimbursable procedures because it is practiced by clinicians of varying specialty throughout the country who achieve

same or similar results by using the same or similar techniques.

Patient-informed consent, as referenced in the AHCPR Guidelines,[13] requires that a physician or doctor inform his or her patient about the procedure that is being recommended and give information about all alternative treatments available. This would include MUA because the literature supports this procedure as safe and effective for certain selected neuromusculoskeletal conditions when performed by certified MUA practitioners, and it supports the use of MUA as an alternative to prolonged conservative manual therapy or surgical intervention when contraindications are not present.[7,9,10]

Is MUA an experimental procedure? Does the definition for "an experimental procedure" apply to this procedure?

From a ruling by Hunter Patrick,[14] District Judge of the Fifth Judicial District of the State of Wyoming, the following is stipulated with reference to a procedure being experimental:

> *Expensive, uncommon, controversial, developing* and *exploring* are not synonyms of *experimental*. Basically, an experiment is a trial or a test, and something that is experimental is something that is in the trial or testing stage. MUA is far beyond the trial or testing stage. It is controversial. It is uncommon in certain parts of the country and common in other parts of the country. It is developing, which is characteristic of virtually any medical or chiropractic procedure. The fact that it is relatively new to one profession does not mean that it is experimental either, and it is not necessarily true that this procedure is as new as it is made out to be.

Because the debate over MUA revolves around the combination of 2 distinct procedures, it seems relevant to determine whether either of the 2 procedures is in itself experimental and whether combining these 2 procedures in any way relegates the combination to the status of *experimental.*

In a proof entitled *Qualification and Use of Chiropractor in Use of Expert Witness,*[15] Sullivan and McCann give the following information on the history of manipulative therapy:

> Scientists have been able to establish that manipulative therapy predates medical therapy. As far back as the aurignacian (17,500 BC), extensive prehistoric cave paintings depict spinal manipulations being delivered. There is evidence that the Chinese used spinal manipulative therapy (2700 BC), as did the Greeks (1500 BC). In fact, there does not seem to be a single origin of manipulative therapy; it was practiced by the Japanese, ancient Egyptians, Syrians, Babylonians, Hindus, and Tibetans. Even American Indian hieroglyphics reveal familiarity with the therapy by such diverse groups as the Sioux, Aztecs, Winnebago, and Mayan Indians.

The other component of the MUA technique is anesthesia. The use of anesthesia or medicinal pain relief was documented as early as the time of Hippocrates. Anesthesia has been around for so long that there is little question about its experimental nature. Because of the advancement of new medications and the use of conscious sedation, the anesthesia element of MUA makes the procedure one of the most easily adaptable neuromusculoskeletal treatment modalities that manual practitioners have at their disposal for chronic and certain acute neuromusculoskeletal problems.

Combining the use of manipulative therapy and anesthesia is not new. As described previously, the CPT code book of reimbursable procedures recognizes the use of manipulation and anesthesia. In fact, the CPT code book lists 10 reference codes for the use of manipulation and anesthesia in such areas as the wrist, elbow, knee, shoulder, ankle, and spine.[12]

MUA is far from being the only medical or chiropractic procedure that involves risks. That it is controversial does not make it experimental; there is nothing new or unique about anesthesia relaxing the muscles, joints, and joint capsules. Because conscious sedation is the anesthesia of choice when performing MUA and because MUA involves qualifying selected patients for the procedure according to the Council on Chiropractic Education–accredited institutional courses and national standards and protocols,[2] there is a precedent set for how the combination of the 2 procedures are performed. Both anesthesiologists and manual practitioners know about these procedural precedents and therefore use sound clinical justification for methods when performing MUA. If a procedure is experimental, it has not been sufficiently tested, it has not been performed by clinicians throughout the United States or abroad with same or similar results, and it has no valid standards of care. Such is not the case with MUA of the spine and extremities. Documentation suggests that there has been clinical investigation, and multiple cases throughout the United States and abroad have documented that this procedure has been performed thousands of times with the same or similar results.

The idea that uniqueness, uncommonness, novelty, controversy, and expense make something experimental is a false notion. When we actually look the terms up in a dictionary, we find that none of these factors have anything at all to do with whether MUA is experimental or not.[14]

Black's Law Dictionary[17] defines experiment as "a trial or special test or observation made to confirm or disprove something doubtful. The process of testing." Tabor's Cyclopedic Medical Dictionary[18] defines experiment as "the scientific procedure used to test the validity of a hypothesis, to gain further evidence or knowledge, or to test the usefulness of a drug or type of therapy that has not been tried previously." The term *experimental* is a word that can be expanded to fill and define as many situations as one may wish; on the other hand, it may also be restricted to the extent that one may desire.

We could easily get carried away and characterize virtually anything medical or chiropractic as *experimental* because there will always be something better tomorrow, and there will also be controversies about what the best procedure is today. For any procedure it is true that the more that is known, the better the procedure. Does continuous evolutionary investigation and improvement in technique mean that a procedure is still investigational or experimental, or does it mean that a procedure is getting better with time and more understanding?

"Courts often remark that the burdens of production and persuasion on an issue rest with the party that pleads the

affirmative on the issue."[14] When the term *experimental* is used by one party to deny a claim by another party, it is incumbent on the first party to justify the use of the term *experimental* by proving that the denial of a procedure is actually because it is *experimental* (true meaning) rather than because it is *controversial.* In other words, you cannot deny a viable procedure that has been shown to be reliable just because you do not like it, or because a company has a policy against reimbursing certain doctors for that procedure.

The reference to MUA being experimental is primarily directed toward the chiropractic physician performing this procedure, in spite of the fact that MUA is not a chiropractic procedure but a multidisciplinary technique. Because most of this argument is based on a reference to MUA within the Mercy Guidelines,[11] we need to discuss this document and the authors' interpretation of it.

The Mercy Guidelines were written in 1993 to give direction to the various procedures used in the chiropractic profession and also to give evolutionary guidance to treatment plans for various conditions. The problem with these guidelines is that they left little room for the evolutionary changes in treatments that were discovered over the years. As with any procedure, treatment modalities improve as more research is done and more clinical outcomes are documented. This is historically a reasonable assumption with any clinical therapeutic modality.

For example, the Mercy Guidelines list MUA as an "equivocal" procedure. According to the guidelines, an "equivocal" listing means "more investigation needed."[11] The word "equivocal" can be referenced in several ways, which is why these guidelines can be so dangerous. If the authors of the Mercy Guidelines wanted to see more research completed to make MUA more understood and improved as a modality for the chiropractic profession rather than being considered more controversial, then their concerns and comments should have been made more concise and pertinent as part of the listing.

As it is, there have been different interpretations by those who seek to deny reimbursement for MUA by claiming it is "experimental" based on the Mercy Guidelines listing. Although the authors of the Mercy Guidelines may have had good intentions, this interpretation of the word "equivocal" has been used against the practitioners who choose to use this modality.

If MUA is broken down into its component parts, particularly those components that a chiropractic physician is responsible for, the procedure is a combination of passive stretch (70%) and articular manipulation (30%). Because both of these procedure are listed as "established" in the Mercy Guidelines, one can only assume that the guidelines are addressing anesthesia as an equivocal part of MUA. Anesthesia is not a chiropractic procedure and never has been; a chiropractic guideline should not have any part in evaluating or interpreting anesthesia. The MUA technique is an intensive manipulative therapeutic modality that takes additional postgraduate training to perform. The technique is only enhanced by adding conscious sedation to the equation. The procedure is a multidisciplinary approach to manipulative therapy that has parts administered by different team members. The anesthesia for conscious sedation is administered by an anesthesiologist. The manipulation portion of the procedure, which involves stretching, mobilization, and manipulation, is performed by an MUA-certified doctor, whether that be a chiropractor, osteopathic, or allopath. The patient's safety, movement, and monitoring for MUA is performed by the operating and recovery room nursing staff. Because this is the generally accepted team approach to MUA,[7,9,16,19-21] a chiropractic guideline should only address the chiropractic portion of the procedure. Additional reference to the anesthesia portion of the procedure should be listed as "with the addition of anesthesia provided by American Society of Anesthesiology standards of care for conscious sedation." Neither established or equivocal procedures make reference to the word "experimental;" therefore, these guidelines are misrepresented if used as a reference for the denial of MUA.

How safe and effective is MUA, and has MUA historically been shown to be safe and effective?

Manipulation under anesthesia has been used as an alternative to prolonged conservative manual therapy and surgical intervention since the late 1930s and has been completed on well over 20,000 patients since that time (number of procedures is based on literature review and clinician interview throughout the United States and the United Kingdom). Because the procedure has been used with regularity on the same types of conditions with similar results over that same period, it falls within the parameters of being both a safe and effective procedure.

Literature reviews, which have been completed on numerous occasions by many authors, indicate that a considerable body of material has been written on the subject of MUA, including references in manual therapy texts. It is important to mention some of the more prominent writers who have supported the use of MUA over the years. Their comments about MUA directly relate to the safety and effectiveness of this procedure and support the findings of others who have indicated that MUA has been used successfully for many years.

Clybourne[5] states, "I have had the opportunity to use manipulation under anesthesia on a sufficiently large number of cases to realize its scope and limitations." Siehl and Bradford[1] wrote a review of 100 MUA procedures on 87 cases and indicated that "the method was first used on those cases which were not responding or were responding very slowly to usual manipulative management." Interestingly enough, Siehl and Bradford also refer to a study om 1038 by Piersol's International Medical Clinic, in which 200 MUAs were performed with a 94% to 97% recovery from nonspecific low back pain.[1] This shows that the 1948 article by Clybourne, although more clinically documented, was not the first article written about this procedure.

In 1963 Donald Siehl wrote, "A conservative regime which includes manipulative treatment of the lower lumbar

intervertebral disc syndrome under anesthesia eventuates in a significantly high percentage of satisfactory results to warrant its use as an essential part of conservative therapy."[3] Dr Siehl presented an 11-year study of 723 cases treated with MUA at the annual meeting of the American Osteopathic Academy of Orthopedics, Bal Harbour, Florida, October 31, 1962.

Lindemann and Rossak[23] concluded that "...it is not permissible to regard the reposition under anesthesia without further ado as technical blunders. It deserves its place in the scale of the orthopedic therapeutic measures for the treatment of the protrusion and the dorso-lateral prolapse in the lumbar region."

In an early presentation at the 39th Annual Session of The American Congress of Physical Medicine and Rehabilitation in 1962, Barber[24] expressed the essence of the controversy surrounding the use of MUAs when he wrote:

> Manipulation is a word used to mean passive movement, forced movement, mobilization, or stretching. Manipulation carried out while the patient is anesthetized, as done by orthopedic surgeons is reputable, but manipulation done on a conscious patient is disreputable in the eyes of the medical profession, because this is the method used by osteopaths and chiropractors.

Because this concept of the right professional providing the right procedure is still used today by many insurance carriers, MUA has not been given the proper chance to prove its efficacy with the frequency that it should have, given the data from clinical outcomes that are being seen throughout the country.[19] Documentation of the safe and effective use of MUA was evident early when Soden[25] described the reason for the use of anesthesia during manipulative therapy by stating, "The answer to the question of 'why anesthesia' lies not only in the successful clinical results, but also in the physiology of anesthesia." This theory has been the foundation of the MUA technique for many years; however, with the advancement and use of new medicines, anesthesiologists are now able to place the patients in conscious sedation. When performed properly, this allows the joint to be mobilized without putting the patient under general anesthesia, which also allows for end range appreciation in joints, joint capsules, and aponeuroses. In fact, I am aware of only a very few facilities in the country that are still using general anesthesia for this procedure. The use of conscious sedation has become the gold standard for MUA now, which makes for a much safer physiological environment for the procedure to be completed.

Krumhansl and Nowacek[26] make the following comment regarding the efficacy of using MUA:

> The importance of fascial lengthening, tendon stretching and ligamentous mobilization are as important as the realignment of joints. Patients with long-standing, intense pain resulting from motor vehicle accidents, industrial accidents and severe falls gradually compensate. Eventually even the 'normal' joints of the spine and proximal extremities become involved. Most frequently there develops a zigzag pattern of muscle tightness and locked facets, either in individual segments or in groups. Manipulation under anesthesia is a final step in a long sequence of medical and physical treatments for patients who have endured prolonged and intractable pain and who have not responded to the more conventional methods of treatment. It is neither new nor revolutionary. Orthopedic surgeons in the United Kingdom have practiced it for many years. Osteopaths in the United States have relied on its efficacy. A few American orthopedists have incorporated this approach into their treatment regimes.

For this last statement they refer to Stoddard,[27] Fisher[28] and Mennell.[29]

Rumney stated that manipulative therapy to the musculoskeletal system under anesthesia has a definite place as an elective modality.[30] "Manipulation of the joints of the spine and the appendages under anesthesia has been carried out by orthopedic surgeons for many years, in both the osteopathic and allopathic professions."

Beckett and Francis[20] reported on a controlled study on MUA completed by Chrisman et al[31] that included 39 patients, all of whom had low back pain, sciatica, and positive findings on at least one sciatic nerve stretch test, with at least one reflex, motor, or sensory deficit finding. By using guidelines from an earlier study by Mensor,[32] 27 of the 39 patients had positive myelograms for disk herniation. The average duration of the symptoms was 6 years, with a range of 10 days to 25 years. For their last attack of back pain, these patients had received conservative management including heat, analgesics, muscle relaxants, bracing, flexion exercises, and rest. These patients then received MUA. A similar group of 22 patients received the same conservative care but no MUA. Chrisman et el[31] reported that "the effects of the MUA were frequently dramatic and more than one half of the patients reported their sciatic symptoms lessened within 24 hours." According to Mensor's criteria,[32] Chrisman et al[31] reported that 21 of the MUA patients had excellent or good outcomes at 5 to 10 months follow-up, 4 patients had fair outcomes, and 14 patients had unsatisfactory results. Overall, they reported that 51% of the patients with an unequivocal picture of ruptured intervertebral disk unrelieved by conservative care had good or excellent results after MUA.[32] The 22 patients who did not have MUA did poorly (no mention of specific results or testing methods), and 16 eventually required surgery. The findings of Chrisman et el were consistent with the findings of Mensor in the earlier study.[31,32] Their findings are also consistent with clinical reasoning that if a procedure has a record of positive patient outcomes and includes similar techniques and procedures from earlier studies, it is hard to argue against its effectiveness, safety, and reliability.

In the article, "Issues Concerning Chiropractic Standards of Practice," Gilkey[34] stated the following:

> Manipulation under anesthesia as a procedure appears to be well within the province of chiropractic. Traditionally, chiropractic's goal has been to restore and maintain the welfare of the human body. In my opinion, MUA fits within that goal since the responsible chiropractor is concerned with appropriateness, necessity, utility, identifiable goals and objectives, utilization standards, protocols, indications, contraindications, patient needs, patient selection, patient safety, defensive practices, collaboration and a (currently limited) scientific basis.[33]

In a 1992 article in the *Journal of the American Osteopathic Association*, Greenman[7] wrote that MUA "is an old widely recognized procedure in musculoskeletal medicine" that has been used for many years to treat musculoskeletal conditions that have been unresponsive to other conservative therapies. In researching the validity of the chiropractor as a prominent provider for this procedure, we learned that Shekelle et al,[35] in a report from a RAND study, found that 94% of the manipulative therapy performed in the United States is by chiropractors. "As part of the chiropractic education there are over 600 hours of basic instruction for manipulative therapy with an additional 8 months of internship with additional training in proctoring requirments to perform manipulation under anesthesia."[9,36] This statement is true, relative to all chiropractic colleges and most states with regard to application by professionals who perform manipulative therapy. To perform MUA, additional postgraduate training is required. This would indicate that the chiropractic physician has specialized skills that may represent higher training skills than other manual practitioners with regard to MUA.

In my articles for the *Florida Chiropractic Association Journal* in 1993 and 1995, I indicated that with the introduction of MUA, certified manual practitioners have another avenue to try if the patient falls into the properly selected categories for MUA.[10,37] "The basic concept behind mobilization, manipulation, and adjusting procedures while the patient is under a sedative/hypnotic is to increase articular, ligamentus, tendonous, and muscular flexibility that has not been achieved in the office therapeutic routine. Standard manipulative techniques are used, but the physiologic state of the patient is changed, and the procedure is done in a different environment. When used on properly selected patients, it is more cost effective and more productive to the patient's return to normal lifestyle than prolonged conservative care or possible surgical intervention."[10]

West et al,[19] commenting on the use of MUA wrote:

> The addition of anesthetic allows for the benefits of manipulation to be shared with those patients who cannot tolerate manual techniques because of pain response, spasm, muscle contractures, and guarding....There has been much discussion regarding the use of general anesthetic in the performance of MUA. Issues discussed include the depth of consciousness associated with general anesthesia, the inability of the patient to give pain feedback or resist over zealous manipulation, and the intrinsic guarding mechanism of voluntary/involuntary muscle fibers, which protect the elastic barrier in the conscious patient.

To address these concerns, Dr West makes the following points:

> First, only highly skilled graduate practitioners who have trained in structural diagnosis and manipulative treatments should perform these procedures. And secondly, the advent of newer, short-acting, highly titratable, and completely reversible intravenous anesthetics allow for controlled anesthesia depths, preservation of patient pain response, as well as significantly reduce morbidity and mortality rates.

Several references in the previously mentioned literature have related to the use of general anesthetics with MUA. The newer concept of conscious sedation, which has been briefly alluded to by Dr West, is important in the discussion of safety and effectiveness of MUA because most of MUAs done in the United States today are being done by using conscious sedation. The anesthetics that are being used are short acting and can be titered to allow for patient response, yet allow for a protective level that permits doctors to complete what they are trying to accomplish with the manipulative technique without allowing tissue damage to occur.

All of the articles I have reviewed and quoted show that MUA has not only been performed for a number of years but has also been investigated both clinically and scientifically. Today, with the advent of newer medications for anesthesia and the formation of the National Academy of MUA Physicians[2] (NAMUAP) in October of 1995, MUA is being recognized as a real alternative to prolonged conservative care or surgical intervention. The NAMUAP has established standards and protocols for the primary practitioner performing MUA (a chiropractic physician in most instances) and has established standards for anesthesia for nursing and for the facilities where MUA is completed. These standards and protocols have begun to be endorsed throughout the United States, primarily by state boards that are interested in addressing the MUA procedure. Most of the state boards of chiropractic have adhered to the provision in their state laws that asserts that procedures that are taught by chiropractic colleges accredited by the Council on Chiropractic Education fall within the scope of practice of a chiropractic physician. Some states have adopted a policy relative to MUA directing specific language in their scope of practice. As an example, in August 1994, the North Carolina Board of Chiropractic stated:

> Manipulation of a patient under anesthesia by an MUA trained chiropractor is within the scope of chiropractic in North Carolina. MUA is an exceptional combination of effective pain management procedures that has expanded the option to help relieve persistent pain. MUA is not an experimental procedure. It is well established within the chiropractic and medical communities and the utilization of MUA has been enhanced by the professional cooperation of these two procedures.[21]

When addressing the safety and effectiveness of any procedure, it is necessary to address any complications as well. Phil Greenman[7] states:

> Temporary flare-ups of symptoms after the procedure have been reported by several patients. This flare-up is attributed to stretching of the adhesion and mobilization of inflamed soft tissue joints. It is easily controlled with appropriate postoperative care. Serious complications have been rare.

He quotes Poppen,[38] who reported the following in 1945:

> [There were] two cases of paralysis after manipulation by competent orthopedic surgeons with the patient under anesthesia. This complication occurred in a population of 400 cases of intervertebral disc disease. It appears that serious complications can be avoided by appropriate patient selection, suitable operative technique by a competent practitioner, and consideration for the contraindications and potential complications.

This demonstrates that the proper selection of cases, as prescribed by accredited certification courses on MUA and the National Standards and Protocols,[2] establishes a precedent for those who perform this procedure. By adhering to these standards for patient care, safety and effectiveness are prominent factors in positive patient outcomes. Many others also believe that the proper approach to any manipulative procedure is the selection of appropriate patients through an examination process, which eliminates potential problems. And it is those manual practitioners with extensive training, such as chiropractic physicians, who make any manipulative treatment less likely to cause harm to the patients.[39]

Another concern within the field of MUA is manipulation of the cervical spine and contraindications for its use in this area. The procedure of MUA in the cervical spine is completed with low-velocity, high-amplitude thrusting procedures that put very little torsion into the cervical spine.[16,39a] The primary focus of MUA in the cervical spine is axial and lateral tractioning and oblique tractioning, with articular cavitation occurring generally during the stretching maneuvers.[16,40] Today, with the use of conscious sedation rather than general anesthesia, the patient is able to discern pain even though neuroperception is slowed down, but end range of muscles and joints are not lost. This allows for full stretching maneuvers and articular cavitation without the inherent risk of vertebrovascular accident, tissue rupture, or joint dislocation. Patients have also undergone prerequisite conservative care for an average of 4 to 6 weeks before the MUA. Because the office form of manipulation is high-velocity, low-amplitude, any damage to the spinal segments or tissues would certainly occur during the office manipulative therapy program. Again, this is why a regimen of conservative manipulative therapy is recommended before considering MUA and why there are very few recorded instances of tissue damage, injury, or even death from MUA. As with any technique that uses forms of anesthesia, there are inherent risks. However, historically there have been very few reports of damage from MUA, and most were from medication reaction or the result of the procedure being performed by uncertified, unskilled practitioners.

The safety and effectiveness of spinal MUA has been widely proven by clinical documentation. The information previously cited relates to the educational standards necessary to perform this procedure,[36] proper patient selection for the procedure, and proper follow-up care once the procedure has been completed. It also relates to the physician being trained to provide proper diagnostic and examination procedures before performing MUA. If all of these standards are followed properly, MUA is safe to perform. It has been performed more than several thousand times, and the effectiveness has greatly outweighed any minimal risks from the types of anesthesia used. All of the malpractice insurance carriers for the chiropractic, osteopathic, and medical professions cover those types of physicians for MUA, which would certainly not be the case if there were any question regarding the safety and effectiveness of this procedure.

What is the current relationship between acute and chronic neuromusculoskeletal spinal pain and the results obtained with MUA?

The current practical status of MUA is the same as it was some 60 years ago except that techniques have been improved. The resistance now taking place is between third party payors and doctors who currently perform MUAs. In 1995, the NAMUAP was formed to help establish Standards and Protocols for the MUA and manipulation under joint anesthesia procedures.[2]

Because these standards and protocols were established by using clinical documentation from earlier studies and present-day clinical outcomes, and because the NAMUAP is now affiliated with the American Academy of Pain Management, it is hoped that although evolutionary improvements are inevitable as more is learned about the MUA technique, the procedure will move into a more scientifically recognized posture of mainstream therapeutics. Because of this standardization of technique, MUA remains scientifically valid based on the concept that any procedure that has proven historic reliability with consistent procedural use must be considered clinically valid. These are established parameters for inclusion in the CPT code book of reimbursable procedures as stated previously.

MUA has been used historically for both acute and chronic conditions. The concept of acute care, however, takes on a different meaning when we speak of MUA. Acute refers to severity and not time as it pertains to MUA; that is, there are many conditions that have recurrent acute exacerbations over the course of the treatment period. This is determined by the patient's perception of pain and is measured subjectively by the doctor with a Visual Analogue Scale and patient questionnaire instruments. Measurement in improvement in many facilities is also objectively obtained by using magnetic resonance imaging, electrodiagnostics, functional capacity testing, and video fluoroscopy. The use of MUA is in itself traumatic on a microtrauma scale. The stretching and articular manipulations that are used during MUA would tend to increase the inflammatory response; thus, MUA is not normally used on acute traumatic cases. There are instances, however, when the patient has unrelenting pain that is interfering with activities of daily living. In these instances, the MUA team might evaluate whether the patient could be brought into the MUA program to gently stretch out the areas and provide relief through increased circulation from passive stretching and medications for pain. The National Academy of MUA Physicians[2] has established parameters for the use of MUA in acute traumatic care. They consider it as having merit in situations in which conservative care that includes forms of manipulative treatment and medical pharmocologic intervention has been tried for a period of 2 weeks and has produced minimal change and progressive deterioration. This treatment varies from the normal MUA and involves coordination with the medical team member to combine pain management with manipulative therapeutics. It has been established that once this acute traumatic care stage has been reached, it usually only takes

1 MUA to bring the patient back to the conservative office program.[16] These cases represent only a fraction of the types of conditions that are normally seen by MUA practitioners.

Historically, the majority of MUA candidates have been those patients with chronic joint restriction from fixation caused by disuse after trauma. This syndrome sets up a vicious cycle that Michael Alter[41] calls the "self-perpetuating cycle of muscle spasm." In this cycle, the patient undergoes trauma, which may be caused by direct contact or through repetitive incremental injuries. These injuries set up pain stimuli, inflammation, emotional tension, sometimes infection, temperature variations, and eventual immobilization from disuse. The cycle then sets up reflex muscle contraction, which if left untreated progresses to muscle contracture. Contracture, in turn, progresses to restricted movement and fixation in the joints, which have a direct effect on what Wyke[42] calls *dysfunctional postural kinesthetics*. Wyke refers to a disturbance in postural kinesthetics as resulting in altered mechanoreceptor response. Typically, Type I, II, and IV mechanoreceptors are concurrently involved, which sets up a cycle of trauma-induced altered posture-affecting movement, which then stimulates nociceptive response. With the MUA technique, stretching maneuvers and mobilization techniques are coupled with specific adjustive techniques to help alter adhesion accumulation that has been laid down by the body as connective tissue to prevent further damage to the areas involved. New medications allow us to perform this technique while the patient is in conscious sedation; thus, we are able to provide progressive linear forces to these areas and alter these adhesions without tearing tissue in the process. Because these medications allow the patient to relax and not respond with immediate muscle contraction when pain is perceived, these maneuvers can be performed so that end range is not lost, the natural protective mechanisms are present but slowed down temporarily, and pain is perceived at a lowered threshold but not remembered.[16,19,43] The anesthesiologist, as a very valuable member of the MUA team, provides just the right medications to allow this physiologic change from the normal office manipulative therapy program. As a result, the certified MUA doctor is able to accomplish considerably more than could be accomplished if the patient were to undergo these procedures in the office setting without conscious sedation.The most important concept here is that if the patient were able to recover in the office setting without the use of conscious sedation, the patient would not have been a candidate for MUA in the first place.

Is a controlled or double-blind study possible with the MUA technique as it is performed throughout the United States? If not, are the documented clinical outcomes being achieved today any less significant?

With the advent of newer medications and more site-specific manipulative techniques being used to perform the MUA technique, the doctor certified to perform MUA today has a considerable advantage in technique. In the 1940s and 1950s, when this procedure was used with regularity by the osteopathic profession, MUA was originally used as an adjunct to orthopedic or osteopathic manipulation techniques that were not working in the office setting. The orthopedic and osteopathic doctors had access to the hospital setting; thus, if a more intensified form of manipulative procedure was warranted in the course of treatment, the doctor could take the patient into the hospital and use anesthesia to complete the manipulations that were deemed necessary to achieve the desired result.

Today, the chiropractic profession has taken up where the osteopaths and orthopedists have left off. With the specific adjustive and manipulative techniques that are taught in chiropractic colleges, the MUA technique is enhanced almost 10-fold[16,44] from the standard office manipulative technique.

Palmeri[45] discusses the difficulty of studying the MUA technique in his masters thesis presented at the 6th Annual National Academy of MUA Physicians conference in New Jersey, May 2001. This was a designed study of MUA and states the following regarding data collection and obtained results:

> Patient selection is difficult because there have not been studies designed to specifically determine that one particular condition is better treated with MUA than with other therapeutic modalities. Although there have been numerous clinical papers written about the technique and the results that have been obtained, specific studies to prove that one condition does better therapeutically than others has not been determined. Documentation concerning MUA however, does show significant outcomes when used with chronic conditions that over the years have shown to be very responsive to this procedure.[45]

There are multiple procedures performed as part of the MUA technique. The procedure involves passive stretch, myofascial release, specific articular adjustive procedures, postural change enhancement (postural kinesthesis), and anesthesia to change the physiologic response so that MUA produces the desired outcome. It is the combination of these techniques, however, that allows MUA to achieve the results that it does.

Clinicians who perform this procedure use different types of manipulative techniques, and one clinician's hands are different from another's. This does not negate the benefit of the hands-on technique but makes it difficult to determine specifically what was done and to duplicate it exactly with another patient.

There are usually multiple areas of the spine or extremities involved in the technique, such as the cervical, thoracic, or lumbar spine. However, the treatment may also involve the cervicothoracic, thoracolumbar, or lumbosacral, or any combination of these areas. If the shoulder is involved, the cervical spine, thoracic spine, and shoulder may be involved. Although these techniques are taught in chiropractic colleges and specific technique courses, the exact duplication of any specific technique for the MUA procedure is not always possible with each condition. In fact, MUA is designed to be condition specific,[16] and the technique is modified according to the specific condition for which it is being used.

Questionnaire instruments for pain evaluation and patient response vary and are not always reliable for every study. A

standard subjective pain questionnaire should be universally recognized for a particular study because some questionnaires are designed specifically for patient pain assessment but are not always accurate for neuromusculoskeletal outcome response.

Chronic pain, even with acute exacerbation, is difficult to study because there are so many variables, especially when psychologic considerations are factored in.

There are very legitimate concerns about the safety of patients and the effectiveness of procedures being used to treat them. Controlled studies or double-blind studies are certainly useful in determining the scientific validity of a procedure. Although manual therapy has been around for centuries, the concern has been to prove its scientific validity the way other scientific studies have been done. The problem is that there are too many human factors involved. Does manipulative therapy in its various forms work? The results of thousands of cases that have been performed by all types of physicians say that it does. There may not as of yet be a clear-cut reason why we get the results we get, but there is no denying that we get these results. The MUA technique is no different. It is considered a form of intensified manual therapy that has been documented by clinicians to be both safe and very effective for certain conditions that have had historically significant responses to the technique. Does the lack of controlled study mean that the MUA technique is any less effective today because we have not been able to "scientifically" document controlled studies? Because MUA is controversial does that make it "experimental," unsafe, or an ineffective procedure? The answers to those questions clearly lie in the patient response and remarkable results that have been achieved with this technique. There are thousands of workers who have returned to work after having MUA when other forms of therapy failed, and thousands of patients who have returned to normal daily living because MUA was used before surgical intervention became necessary. The real "study" is the patient population's response to the MUA technique over the years. This can be determined by the countless articles written about MUA, which are documented in this article, and by the large numbers of MUA candidates that have come and gone with better outcomes because of the MUA technique. The significance of MUA is that it has been found to be very safe and effective and has achieved remarkable results for more than 60 years. A technique that has been used by multiple practitioners for a long time with similar results and outcomes and that is listed in a reputable manual of reimbursable expenses cannot be addressed as an investigational or an experimental procedure. It is time for a re-evaluation of MUA, one that is based on patient appreciation and clinical outcome. The MUA technique is not harming the public but, rather, helping thousands to return to more healthy lifestyles, in many cases far earlier than with other more traditional types of conservative therapy. Why are we debating a procedure that has so much to offer with very little hazard? Why is there so much controversy over who performs the procedure when those who are certified to perform this procedure are producing remarkable results that are less expensive than prolonged conservative care or possible surgical intervention? Are we basing decisions for this therapeutic modality on results or rhetoric? Are we still concerned with patient response or who provides the service? I would hope the answers to these questions are obvious.

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Attachment C

Supplemental Care With Medication-Assisted Manipulation Versus Spinal Manipulation Therapy Alone for Patients With Chronic Low Back Pain

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ABSTRACT

Objectives: To measure changes in pain and disability for chronic low-back pain patients receiving treatment with medication-assisted manipulation (MAM) and to compare these to changes in a group only receiving spinal manipulation.

Study Design: Prospective cohort study of 68 chronic low-back pain patients.

Methods: Outcomes were measured using the 1998 Version 2.0 American Association of Orthopaedic Surgeons/Council of Musculoskeletal Specialty Societies/Council of Spine Societies Outcomes Data Collection Instruments. The primary outcome variable was change in pain and disability. All patients received an initial 4- to 6-week trial of spinal manipulation therapy (SMT), after which 42 patients received supplemental intervention with MAM and the remaining 26 patients continued with SMT.

Results: Low back pain and disability measures favored the MAM group over the SMT-only group at 3 months (adjusted mean difference of 4.4 points on a 100-point scale, 95% confidence interval [CI] −2.2 to 11.0). This difference attenuated at 1 year (adjusted mean difference of 0.3 points, 95% CI −8.6 to 9.2). The relative odds of experiencing a 10-point improvement in pain and disability favored the MAM group at 3 months (odds ratio 4.1, 95% CI 1.3-13.6) and at 1 year (odds ratio 1.9, 95% CI 0.6-6.5).

Conclusion: Medication-assisted manipulation appears to offer some patients increased improvement in low back pain and disability. Further investigation of these apparent benefits in a randomized clinical trial is warranted. (J Manipulative Physiol Ther 2005;28:245-252)

Key Indexing Terms: *Manipulation, Chiropractic; Low Back Pain; Medication-Assisted Manipulation; Manipulation Under Anesthesia*

Studies of medication-assisted manipulation (MAM) techniques have appeared in the literature since 1930.[1] Manipulation under anesthesia (MUA),[2-5] manipulation under joint anesthesia/analgesia,[6,7] manipulation under epidural anesthesia,[8] and various injection procedures combined with manipulation therapy[9,10] represent examples of MAM techniques. These protocols have been recommended for a variety of spine-related pain conditions, including chronic lumbosacral and sacroiliac strain,[1,11] acute and chronic low back pain,[9,10,12-15] recalcitrant low back pain and lumbar radiculopathy,[6,8] spinal arthritis,[1,16] sciatica,[1,17] lumbar disk syndrome,[16,18-22] myofibrositis with and without disk herniation,[16,19] postoperative stiffness,[16,23] spondylolisthesis,[16] constant intractable pain,[24] and failed back surgery syndrome.[25]

Osteopaths and orthopedic practitioners typically administered early MAM techniques using long-lever (ie, using the leg or thigh to increase the rotatory force) spinal maneuvers performed with the patient under general anesthesia. Current protocols use specific short-lever (ie, hand to spine) spinal adjustments and mobilization, characteristic of chiropractic and modern osteopathic adjustive techniques, after the administration of shorter acting intravenous sedation and analgesia.[26] Recent studies have investigated currently used MAM protocols, but none have included long-

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term follow-up using a comprehensive set of previously validated measures.

The objectives of this study are (1) to measure immediate and long-term changes in pain and disability for chronic low-back pain patients receiving supplemental treatment with a MAM protocol combining mobilization, spinal manipulation therapy (SMT), and traction therapy of the sacrococcygeal structures; and (2) to compare changes in pain and disability for chronic low-back pain patients receiving supplemental care with MAM to changes in pain and disability for chronic low-back pain patients receiving only a course of usual SMT.

Methods

Study Design and Source Population

Chronic low-back pain patients presenting at 2 private chiropractic practices were recruited for participation in a prospective observational cohort study. Recruitment targeted existing patients and was augmented by radio and newspaper advertisements as well as direct mailings to local physicians requesting referral of appropriate patients. All patients enrolled in the study received an initial 4- to 6-week course of SMT and then followed 1 of 2 potential treatment options: (1) continued care with usual SMT or (2) continued SMT supplemented with MAM procedures.

Allocation to study group was based on clinician recommendation and patient self-selection following re-evaluation after the initial course of SMT. Study participants were followed up for 1 year, with data collected at baseline, 6 weeks, 3 months, 6 months, and 1 year. The source population was made up of adults in the areas served by the 2 chiropractic practices (one located in an urban area of Southern California, the other located in a rural area of Northern California).

Patient Selection

Patients were eligible for the study if they (1) sought care at 1 of the 2 private chiropractic practices from August 20, 2000, to February 5, 2002, (2) presented with chronic (duration >3 months) nonspecific low back pain with or without back-related leg pain, (3) had reduced lumbopelvic flexibility as shown by an inability to touch their fingertips to the floor while maintaining a straight-legged standing posture, and (4) were between the ages of 18 and 60 years.

Potential participants were excluded if they (1) had back pain caused by fracture, tumor, infection, severe spondyloarthropathy, or other nonmechanical cause, (2) had active rheumatoid disease, (3) had any active infectious disease, (4) had a current history of smoking or tobacco use (must not have used tobacco products for at least 6 months before presentation), (5) had a current history of drug and/or alcohol abuse, (6) had severe coexisting disease, (7) had a blood coagulation disorder or were using corticosteroids or anticoagulant medications, (8) were using any form of medication that would conflict with sedating medication as determined by board-certified anesthesiologist members of the treatment team, (9) had any conditions that would preclude the use of manipulation and MAM procedures, (10) lacked the ability to read English, or (11) had low back pain involving third-party liability or worker's compensation.

Patient Screening and Enrollment Protocol

A field coordinator interviewed all patients presenting with chronic low back pain to identify those meeting selection criteria. A brief explanation of study goals and treatment protocols was given to all patients satisfying inclusion criteria. Eligible patients were asked if they were willing to participate in a study designed to help determine effective care for people with low back pain by assessing 2 treatment strategies aimed at reducing pain, improving physical function, and increasing patient satisfaction with treatment. The field coordinator explained that all study participants would receive an initial course of SMT that might be followed by supplemental care with MAM. It was explained that final decision regarding treatment rested with the patient and treating doctor. Patients agreeing to participate in the study received a medical history interview and physical examination. Plain film radiographs and magnetic resonance imaging radiographs were performed before treatment.

Informed Consent

All eligible patients electing to participate in the study were asked to read and sign an informed consent form. The 5-page informed consent form provided explicit detail regarding treatment protocols, potential benefits, potential complications, and possibility of treatment failure. The informed consent form clearly stated that participation in the study was voluntary and that the patient could withdraw from the study or choose alternative treatment at any time. The institutional review board at the Southern California University of Health Sciences approved the study protocol and informed consent form. A field coordinator administered the informed consent form and was available to answer study-related questions. In addition, a clinician met with all eligible patients to provide a detailed explanation of the MAM protocol.

Cohort Selection

All study patients received a 4- to 6-week course of SMT. Patients were then reevaluated after the initial treatment period. Based on the patient's clinical progress, treating clinicians made recommendations regarding additional care that included continued spinal manipulation or supplemental care with MAM. Ultimate decisions regarding choice of treatment group resided with the patient.

Treatment Protocols

Care was provided by 2 chiropractors using similar treatment protocols. For the initial 4 to 6 weeks, SMT was provided to all patients, as well as information about posture and body mechanics and 1 or more of the following, as appropriate: flexibility, aerobic, and strengthening exercises. On average, patient visits were scheduled 2 to 3 times per week during this initial phase of treatment.

Patients were reevaluated at the end of the initial 4 to 6 weeks. Based on the results of this reevaluation, the clinician had 3 options: (1) recommend continued care with spinal manipulation, (2) recommend supplemental care with MAM, or (3) discharge the patient. Supplemental care with MAM was recommended if the initial clinical goals (eg, range of motion, muscle strength, and pain relief) were not met with the course of SMT and the clinician felt further gains likely with the addition of MAM.

Spinal manipulation therapy only. Patients in this group continued to receive SMT similar to the initial phase of treatment. Spinal manipulation involves a controlled dynamic thrust, applied with high velocity and low amplitude, directed at 1 or more joints of the spine using short-lever contacts. Continued care was provided based on clinical evaluation and patient feedback for an additional period of 4 to 12 weeks.

Medication-assisted manipulation. After the initial 4 to 6 weeks of spinal manipulation, patients in this group received 1 to 3 treatments with MAM. Typically, these sessions were provided in consecutive weeks. Medication-assisted manipulation incorporates the intravenous administration of sedative and analgesic medication. The rationale for the addition of sedative and analgesic medication to SMT is that it helps to eliminate or reduce pain and muscle spasm that hinder the effective use of traditional manipulation and mobilization. It is perceived that these procedures allow the practitioner to break up joint adhesions and reduce segmental dysfunction to a greater extent than if medication had not been used. A medical physician with board certification in anesthesiology carefully examined the patients to determine if relaxation and pain-controlling medication were appropriate.

The medication (ketamine hydrochloride and midazolam hydrochloride) delivered enough relaxation and pain relief to make the treatment comfortable, but was designed to wear off quickly. The examination and treatment while under medication took approximately 10 to 20 minutes. While in the relaxed state, the patients underwent a series of spinal and pelvic mobilization maneuvers targeted at increasing joint flexibility and overall range of motion. Cautious administration of SMT was used as indicated. In addition to these elements common to current medication under anesthesia protocols, patients received traction therapy with the intention of improving the movement of sacrococcygeal structures.[27] Patients in this group also continued office visits in support of the MAM results.

Data Collection and Variables

Data were collected using the 1998 Version 2.0 American Association of Orthopaedic Surgeons/Council of Musculoskeletal Specialty Societies/Council of Spine Societies Outcomes Data Collection Instruments.[28] Working with other specialty societies, the American Association of Orthopaedic Surgeons developed a series of instruments designed to collect patient-based data within clinical practices to assess the effectiveness of treatment regimens and in musculoskeletal research settings to study the clinical outcomes of treatment. The lumbar spine module (as well as 10 other primary instruments included in the normative data study and outcomes instruments) is designed to assess the degree to which a patient's condition affects physical and emotional functioning, self-image, and symptom status. In addition, the lumbar spine instruments include the Short-Form 36-Item (SF-36) Health Status Questionnaire.[29] Scales in the instruments rely on multitrait/multi-item response analysis and exhibit high levels of internal reliability and discriminant and convergent validity.[30] Each instrument contains a number of questions; some may be assessed individually, and others may be combined to form scales. Each summated outcomes scale is composed of the scores from related items that are averaged and then rescaled so that each is scored from 0 (poor outcome) to 100 (best possible outcome).

The following data were collected at baseline.

Low back pain and related disability. The pain/disability scale consisted of 11 items, 2 of which questioned the patient about frequency and magnitude of back pain symptoms. The remaining 9 items pertained to impact of these symptoms on activities of daily living (ADLs). Responses to these 11 items were averaged and rescaled to a 100-point scale with a score of 0 representing the most possible pain and disability and a score of 100 representing least possible pain and disability.

Treatment expectations. The treatment expectations scale was derived from responses to 5 items that queried the patient regarding expectations of treatment at baseline in terms of impact on ADLs. On the baseline questionnaire, these items were prefaced by the question, "What results do you expect from your treatment?" In response to the specific ADL items, the patient circled a number from 1 to 5 that represented their belief in the level of likelihood that the treatment would provide improvement. Patients were also given the choice of "not applicable" for these items. The index was scaled so that a score of 0 represents the lowest level of treatment expectations and 100 represents the highest level of treatment expectations.

Comorbidity. The comorbidity index is composed of the scores from related items that were averaged and rescaled so

that each is scored from 0 (no comorbidities) to 100 (highest level of comorbidities). Patients provided information regarding presence of major comorbidities, treatment status regarding any comorbidities, and whether existing comorbidities limited activities.

Health-related quality of life. The lumbar spine module contains the SF-36 Health Survey, Version 2 (SF-36v2), which measures general health-related quality of life.[29] Five of 8 subscales measuring domains of health were used: (1) physical functioning, (2) role limitations caused by physical health, (3) role limitations caused by emotional problems, (4) general health perceptions, and (5) mental health. All 5 measures are scored on a 0- to 100-point scale.

Sociodemographic data. Sociodemographic variables included age, sex, race/ethnicity, education, household income, marital status, and current employment status.

Follow-up questionnaires addressed the same items measured at baseline. Repeated presentation of the various questions and scales provided information about change from baseline. Visit frequency was tracked by review of study patient files in both offices.

Outcome Variables

The primary outcome variable was change in pain and disability measured with a 0-point (most pain and disability) to 100-point (least pain and disability) scale. The pain and disability outcome was treated as a continuous variable when measured with the pain/disability index. This outcome was also used as a dichotomous variable. Cut points of 10 points or more (vs <10 points) on the 100-point scale were used as dichotomous outcomes. The 10-point cut point was chosen a priori as the smallest change felt to be clinically meaningful for pain and disability.

Statistical Analysis

The primary comparison was MAM versus SMT alone. Descriptive statistics were used to summarize the patient characteristics measured at baseline for both treatment groups. Mean values, SDs, and medians were computed for continuous variables, and frequency distributions were generated for categorical variables. Time trends of continuous outcome variables within each group were graphed, and differences from baseline measurements were computed and plotted by time. Adjusted mean differences and 95% confidence intervals (CIs) (controlling for potential differences between groups suggested by comparison of baseline data) between groups on continuous variables were computed at each data collection point.

Logistic regression was used to estimate odds ratios (ORs) and 95% CIs for the likelihood of experiencing at least a 10-point improvement in pain and disability between baseline and the 3-, 6-, and 12-month follow-up intervals. Sample size justification was based on detecting a 10-point difference in pain/disability index scores between groups. An a priori judgement was made that a difference less than 10 points on the pain/disability index would not be clinically meaningful. Sample size calculations suggested that an overall sample size of 80 subjects, 40 subjects per treatment group, would be sufficient to detect between-group differences of 10 points in pain and disability (80% power and $\alpha = .05$). The sample size necessary to detect smaller and probably not clinically significant differences would be substantially larger (eg, detection of 5-point between-group differences would require an overall sample size of 260 subjects with 80% power and $\alpha = .05$).

Results

Screening, Enrollment, and Follow-up

A total of 314 patients were screened. Two hundred eighteen were excluded for failure to meet selection criteria. Of the 96 patients eligible for the study, 70 elected to participate. Two dropped out, 1 from each office, after completing the consent form, but before receiving treatment. Total enrollment in the study consisted of 68 patients with both sites contributing 34 patients each. Forty-two patients elected to receive supplemental care with MAM, whereas 26 patients elected to continue with SMT alone.

Six-week and 3-month follow-up questionnaires with complete outcome data were returned by all 68 (100%) patients. Sixty-two (91.2%) patients returned the 6-month questionnaires, and 63 (92.7%) patients completed the 1-year questionnaires.

Baseline Characteristics

Table 1 shows baseline distributions of sociodemographic, health status, and low-back pain characteristics by treatment group and for all patients. Some variable categories were collapsed to facilitate statistical comparison between groups. Overall, 62% of the participants were men, and the mean age of all patients was approximately 41 years. Study patients were predominantly white, non-Hispanic (83.8%), married (64.7%), employed (91.2%), and had at least some college education (87.8%). The mean pain/disability score for all patients was 65 (on a 0- to 100-point scale, 100 representing least pain and disability).

Table 1 suggests that both groups appear similar for most characteristics measured. The overall mean treatment expectations score was 82.5 (on a 0- to 100-point scale, 100 points signifying greatest optimism regarding treatment results) with very similar expectations reported by both treatment groups (83.9 vs 80.0 for MAM and SMT groups, respectively). Age, general health status, marital status, employment status, income, comorbidity, satisfaction with current symptoms, and SF-36 scores across all subscales were not appreciably different (P values ranging from .13 to .89).

Table 1. *Frequency distributions and mean values and medians for selected sociodemographic and baseline health status and back pain variables, by treatment group*

	Total (n = 68), n (%)	Treatment group		Significance level
		MAM (n = 42)	SMT (n = 26)	
Age, y				
21-29	10 (14.7)	8 (19.0)	2 (7.7)	
30-39	21 (30.9)	13 (31.0)	8 (30.8)	
40-49	23 (33.8)	15 (35.7)	8 (30.8)	$P = .303$
50-59	14 (20.6)	6 (14.3)	8 (30.8)	
Mean (SD)	41.2 (9.33)	40.0 (9.38)	43.2 (9.08)	
Median	42.7	39.1	44.2	
Sex				
Male	42 (61.8)	22 (52.4)	20 (76.9)	$P = .043$
Female	26 (38.2)	20 (47.6)	6 (23.1)	
Race/ethnicity*				
White, non-Hispanic	57 (83.8)	38 (90.5)	19 (73.1)	
Black or African American	1 (1.5)	0 (0)	1 (3.8)	
Hispanic	5 (7.4)	3 (7.1)	2 (7.7)	–
Asian or Pacific Islander	2 (2.9)	0 (0)	2 (7.7)	
Other	3 (4.4)	1 (2.4)	2 (7.7)	
Education				
High school grad/some college	33 (50.0)	22 (53.7)	11 (44.0)	$P = .447$
College grad/postgraduate school or degree	33 (50.0)	19 (46.3)	14 (56.0)	
Marital status				
Married	44 (64.7)	24 (57.1)	20 (76.9)	
Living with significant other	9 (13.2)	6 (14.3)	3 (11.5)	$P = .359$
Divorced/separated	6 (8.8)	5 (11.9)	1 (3.8)	
Single (never married)	9 (13.2)	7 (16.7)	2 (7.7)	
Employment status				
Currently working, homemaker, student	63 (92.6)	38 (90.5)	25 (96.2)	$P = .383$
Unemployed, leave of absence, retired	5 (7.4)	4 (9.5)	1 (3.8)	
Household income				
Less than US$20 000	4 (7.1)	3 (9.1)	1 (4.3)	
US$20000 to US$39999	14 (25.0)	11 (33.3)	3 (13.0)	
US$40000 to US$59999	16 (28.6)	10 (30.3)	6 (26.1)	$P = .134$
US$60000 to US$79999	9 (16.1)	5 (15.2)	4 (17.4)	
US$80000 or more	13 (23.2)	4 (12.1)	9 (39.1)	
General health status				
Excellent	12 (17.6)	7 (16.7)	5 (19.2)	
Very good	29 (42.6)	14 (33.3)	15 (57.7)	$P = .155$
Good	22 (32.4)	17 (40.5)	5 (19.2)	
Fair	5 (7.4)	4 (9.5)	1 (3.8)	
Comorbidity index (0- to 100-point scale), mean (SD)	8.8 (4.77)	8.8 (4.86)	8.7 (4.72)	$P = .897$
Treatment expectations (0- to 100-point scale), mean (SD)	82.5 (17.9)	83.9 (17.7)	80.0 (18.5)	$P = .398$
Pain/disability index (0-100 scale), mean (SD)	65.0 (14.6)	60.7 (13.3)	72.0 (14.0)	$P = .001$
Satisfaction with symptoms				
Very dissatisfied	48 (70.6)	31 (73.8)	17 (65.4)	
Somewhat dissatisfied	13 (19.1)	7 (16.7)	6 (23.1)	$P = .889$
Neutral	5 (7.4)	3 (7.1)	2 (7.7)	
Somewhat satisfied	2 (2.9)	1 (2.4)	1 (3.8)	
SF-36, mean (SD)				
Physical function	70.1 (20.4)	68.7 (19.1)	72.5 (22.5)	$P = .457$
Role-physical	47.8 (39.1)	44.5 (38.5)	52.9 (40.2)	$P = .397$
Role-emotional	72.6 (38.9)	71.5 (38.4)	74.4 (40.3)	$P = .775$
Mental health	73.1 (15.8)	72.4 (16.6)	74.2 (14.8)	$P = .649$
General health	71.7 (20.8)	71.7 (20.8)	74.0 (21.5)	$P = .471$

Some patients refused to provide data for some variables. Percentages were calculated using total number of nonmissing responses provided for each variable.

* Lack of racial diversity in study patients precluded meaningful analysis comparing differences between groups.

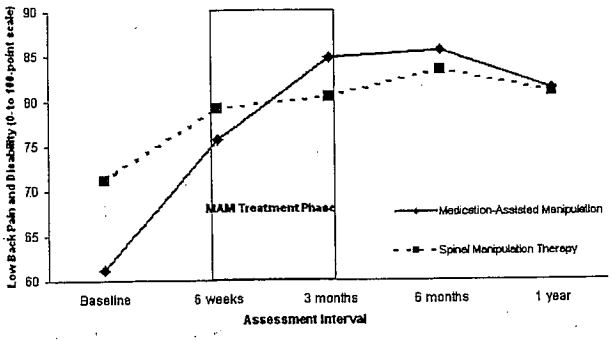

Fig 1. *Adjusted mean levels of pain and disability, by follow-up assessment and treatment group.*

Table 2. *Adjusted mean values, mean differences, and 95% CIs for pain and disability at baseline and each follow-up assessment, by treatment group: results of ordinary least squares regression analysis*

Follow-up interval	Mean pain/disability		Mean difference*	95% CI*
	MAM	SMT		
Baseline	61.2	71.2	−10.0	−16.9 to −3.1
6 wk	75.7	79.2	−3.6	−10.8 to 3.7
3 mo	84.8	80.4	4.4	−2.2 to 11.0
6 mo	85.6	83.4	2.1	−6.1 to 10.4
1 y	81.3	81.0	0.3	−8.6 to 9.2

Baseline pain and disability mean scores, mean difference, and 95% CI for the MAM and SMT groups are unadjusted. Follow-up pain and disability means, mean differences, and 95% CIs are adjusted for baseline pain/disability and sex.

* Negative values indicate higher scores for the SMT group relative to the MAM group.

Some differences in clinical and sociodemographic variables were noted between the 2 treatment groups at baseline. The MAM group reported a mean pain/disability score of 60.7, whereas the SMT-only group reported a mean pain/disability score of 72.0 (mean difference −11.3, 95% CI −18.1 to −4.6). Differences between the treatment groups for sex also appear statistically significant with a higher proportion of women opting to supplement SMT with MAM. Subsequent analyses comparing pain/disability outcomes between groups controlled for baseline differences in pain/disability and sex.

Pain/Disability Outcomes

Adjusted mean pain/disability scores for both groups are presented for all assessment intervals in Fig 1 and Table 2 (adjusted for baseline pain/disability and sex). Improvement in adjusted mean pain/disability scores during the initial 4- to 6-week trial of therapy was 8.0 points for the patients choosing to continue with SMT alone, whereas the patients opting for supplemental care with MAM experienced a gain of 14.5 points during the initial SMT phase. During the subsequent active care phase (from week 6 to 3 months), the group receiving additional care with SMT alone experienced a slight further improvement of 1.2 points, whereas the group receiving supplemental care with MAM experienced a substantially larger additional improvement in pain and disability scores of 9.1 points. At 3 months, the adjusted mean pain and disability score for the MAM group increased to 84.8, whereas the usual care group score remained virtually unchanged at 80.4 (adjusted mean difference of 4.4 points, 95% CI −2.2 to 11.0). Slight increases in adjusted mean pain and disability scores occurred between 3 and 6 months for both groups, with scores dropping a little for both groups at 1-year follow-up.

Table 3. *ORs for improvement in pain and disability for MAM versus SMT, by follow-up interval: results of logistic regression analysis*

Follow-up interval	OR*	95% CI*
0-3 mo	4.1	1.3-13.6
0-6 mo	2.5	0.7-9.9
0-12 mo	1.9	0.6-6.5

Odds of improvement in pain/disability scores from baseline to each follow-up assessment point for the MAM group versus the SMT group. Improvements of ≥10 points (vs <10 points) on the pain and disability index were used as dichotomous outcomes.

* ORs and 95% CIs are adjusted for baseline pain/disability and sex.

About 66% of all patients experienced improvement in pain and disability by 10 points or more during the first 3 months, and approximately 64% of study participants reported improvement of at least 10 points at 1 year. Eighty-one percent of the MAM group had a 10-point or more improvement in pain and disability scores between baseline and 3 months compared with 42% of SMT-only patients. At 1 year, 74% of the MAM group reported an improvement of at least 10 points over baseline scores compared with 48% of the patients continuing with SMT alone. Table 3 lists the adjusted ORs measuring the odds of improvement by at least 10 points for pain and disability in the MAM group versus the SMT group. The relative odds of experiencing a 10-point improvement in pain and disability favored the MAM group at 3 months (adjusted OR 4.1, 95% CI 1.3-13.6) and at 1 year (OR 1.9, 95% CI 0.6-6.5).

There were no known study-related adverse events requiring institutional review board notification for participants in either group.

Discussion

This effort represents the first multisite long-term study of MAM using a comprehensive set of previously validated outcome measures. A recent review of MAM lists at least

25 studies appearing in the English-language literature since 1930.[26] The vast majority of these studies are case reports or case series,[2-4,16,18-20,23-25,31-34] with only 1 cohort[35] and 2 randomized clinical trials.[9,10] One additional cohort study has appeared since the review was published.[36] Although our findings of patient improvement with MAM are similar to the findings of prior investigations, significant differences between many of those trials and this present study, perhaps most notably differences in treatment protocols, limit meaningful comparisons.

Most reported MAM studies involve MUA techniques, and virtually all MUA reports published before the mid-1990s included protocols using general anesthesia. More current protocols, including the one used in this investigation, use shorter acting agents that induce moderate sedation/analgesia (conscious sedation) to deep sedation/analgesia rather than general anesthesia, which causes loss of consciousness during which patients are not arousable, even by painful stimulation.

In addition, these earlier studies used long-lever manipulation techniques rather than the short-lever techniques currently used. The earlier studies did use passive range of motion stretching similar to current techniques. The 2 MAM randomized clinical trials reported protocols differing even more substantially. One studied the use of long-lever manipulation accompanied with the injection of a proliferant solution into spinal ligaments,[9] and the other investigated the combination of manual therapy with steroid injections of the piriformis muscle.[10]

Two recent studies used treatment protocols quite similar to this observational trial. One reported results from a case series of 177 patients,[2] and the other reported results from a cohort study with 38 MUA patients compared with 49 MUA-eligible patients not receiving such treatment because of failure to obtain insurance precertification.[36] The case series outcome measures were range of motion, Visual Analog Scale rating, medication use, and work status assessed before MUA, after MUA, and 6 months after MUA. The cohort study outcome measures assessed low back pain and disability using the Roland-Morris Questionnaire and a numerical pain scale given before MUA, after the final MUA, and again 4 weeks later. Findings from our study are consistent with these 2 prior investigations regarding improvement in reported pain and disability. A pattern common to the recently published cohort study and our study is that mean baseline pain and disability scores were worse in the MAM cohort relative to the SMT-only cohort.

Treatment group selection was dependent on insurance approval in the recently published MUA cohort study. Impact of financial constraints was limited in our study by the existence of a funding source that provided for care at subsidized rates. In our study, group determination was the result of patient choice following clinical recommendations made at reevaluation after the initial trial of usual chiropractic care. Clinicians did not have access to pain/disability index scores at any time during the study, but mean pain/disability score differences at baseline between MAM and SMT-only groups appear to agree with the clinicians' assessments as well as underscore a theme in the MAM literature. This procedure has been recommended as an additional treatment option for patients with greater levels of pain and disability that are not adequately resolved with manual therapy alone.

The primary limitation of the present investigation is that treatment was not randomly allocated. This limitation was partially addressed by collecting extensive patient characteristics data and controlling for observed differences between the 2 groups during analysis. Baseline data indicate that the 2 groups are quite similar across most variables, with the notable exception of level of initial pain and disability and potential differences in age and sex, which were used as a covariates in all subsequent analyses. Resource limitations resulted in an enrollment lower than original recruitment targets resulting in less precise estimates of effect. Results from our study may not be generalized to other populations in which patient populations differ from our sample or clinicians use different techniques. The MAM protocol applied in this study is very similar to those taught at postgraduate courses in the United States, although the additional component of traction therapy for sacrococcygeal structures is unique. Both clinicians serve as or have served as faculty for postgraduate MAM courses. The use of previously validated comprehensive outcome measures instruments, long-term follow-up, and high 1-year response rate represent strengths of this study relative to prior MAM investigations.

Conclusion

Chronic low-back pain patients presenting with greater levels of pain and disability appear more likely to pursue supplemental care with MAM after a course of SMT alone. Medication-assisted manipulation appears to offer these patients increased improvement in low back pain and disability. These improvements may not endure over the long term, and the clinical changes observed are not necessarily caused by MAM. This study does suggest that certain subpopulations of chronic low-back pain patients may be suitable candidates for MAM and that additional studies assessing treatment effectiveness appear warranted. A larger-scale, multisite, randomized, controlled trial represents the next logical step for subsequent investigations of MAM.

Acknowledgments

The authors thank Mr Michael Marcus for the funding of this project through a generous research gift. The authors also thank Dr Jim Wooley, Dr Chris Kemper, Dr Brian

Gamett, and Mr Andy Hobbs for their support throughout this project, particularly during the clinical phase.

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KATHLEEN S. CREASON, MBA
EXECUTIVE DIRECTOR

D.O.s: Physicians Treating People, Not Just Symptoms

February 23, 2009

April Alameda, Program Analyst
California Board of Chiropractic Examiners
2525 Natomas Park Drive, Suite 260
Sacramento, California 95833

RE: Proposed Regulatory Language for Chiropractic MUA

Dear Ms. Alameda,

The Osteopathic Physicians & Surgeons of California (OPSC) appreciates the opportunity to submit comments regarding the proposal of the California Board of Chiropractic Examiners to establish Standards of Care for Manipulation Under Anesthesia (MUA).

OPSC remains firmly opposed to these proposed regulations, due to concerns about patient safety as well as legal prohibitions against chiropractors performing MUA.

OPSC's greatest concern is that chiropractic education does not provide appropriate medical training to adequately care for patients undergoing MUA. In addition to the risks inherent with anesthesia, the inability of the patient to provide feedback while under anesthesia increases the potential for significant injury. Indeed, the guidelines approved for the treatment of workers' compensation injuries in California, the Occupational Medicine Practice Guidelines, Second Edition, on page 300 express concerns about MUA, "... because high quality studies do not exist and the procedure has significant associated risks".

The American Academy of Osteopathy, in its Consensus Statement for Osteopathic Manipulation of Somatic Dysfunction under Anesthesia and Conscious Sedation, specifies that MUA is contraindicated in the presence of:

- primary or metastatic carcinoma in the area to be treated
- local bone or joint infection in the area to be treated
- acute fracture
- unstable spondylolisthesis
- acute inflammatory arthritis
- uncontrolled diabetic neuropathy
- evidence of spinal cord compression by tumor or disc herniation
- evidence of aortic aneurysm
- contraindications to general anesthesia or IV sedation and
- any condition that would contraindicate direct manipulative techniques which would likely result in harm to the patient

Chiropractic education does not support the ability to identify or diagnose many of these contraindications, resulting in a direct threat to patient safety. MUA, if undertaken at all, should only be performed by a licensed osteopathic or medical physician fully trained to manage the associated risks and potential complications.

In addition to significant patient safety concerns, OPSC opposes these proposed regulations from a legal standpoint; chiropractors are prohibited from performing procedures such as MUA in which medication is an essential component. Section 7 of the Chiropractic Initiative Act specifically prohibits "use of any drug or medicine now or hereafter included in materia medica". (Initiative Measure, Stats. 1923, p. xc, § 7). OPSC asserts that the use of anesthesia, which is medicine included in materia medica, is integral to the performance of MUA. Therefore, chiropractors are prohibited under their authorizing initiative from conducting this procedure. The statement contained in the proposed regulations specifying that anesthesia may only be administered by a California licensed physician and surgeon or other health care provider authorized under law to administer anesthesia does not mitigate the fact that the procedure could not be performed without the use of medicine.

OPSC strongly opposes these proposed regulations.

Sincerely,

Kathleen S. Creason, MBA
Executive Director

RIVERSIDE COUNTY
REGIONAL MEDICAL CENTER

DEPARTMENT OF ANESTHESIA

February 23, 2009

To Whom It May Concern:

As an Osteopathic physician and an anesthesiologist, I respectfully oppose the Board of Chiropractic Examiners' proposal to adopt California Code of Regulations Division 4, Title 16, Section 361 "Manipulation Under Anesthesia".

I have serious concerns about the safety of patients who undergo manipulation under anesthesia (MUA). Even manipulation without anesthesia is not risk-free, as there have been documented cases of catastrophic outcomes in non-anesthetized patients. General anesthesia will render a patient insensitive to pain and cause their muscles to relax. There are real risks because the patient cannot tell the provider when they are in discomfort (in danger). Furthermore, the muscle relaxation that is induced will alter the usual palpatory findings and again, increase the risk of a complication.

If MUA is undertaken at all, it should be performed only by a licensed physician. A classic example of an accepted MUA indication would be taking a shoulder joint through its range of motion in a patient with adhesive capsulitis. This procedure is usually done by an orthopedic surgeon who is well-trained in this very sub-specialized area and is completely capable of taking care of any complications that may arise. As such, this MUA constitutes a practice of medicine and is entirely outside the scope of chiropractic care. Additionally, since chiropractors do not have admitting privileges to most hospitals, the question arises of who would admit and care for these patients should a serious complication occur.

As indicated above, it is only licensed California physicians (M.D./D.O.) with appropriate residency training, who are considered qualified to perform MUA for well-documented clinical indications such as adhesive capsulitis of the shoulder. Research in the field supports this position as do many reputable organizations, such as the American Society of Anesthesiologists. It is clearly outside the scope of practice to consider this safe and effective for the chiropractic doctor to perform such procedures.

Therefore, I strongly urge the Board of Chiropractic Examiners **not** to move forward with regulations proposing to authorize chiropractic "Manipulation Under Anesthesia".

If you have any questions on this matter, please do not hesitate to contact me.

Sincerely,

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Chair
Department of Anesthesia

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California Medical Association
Physicians dedicated to the health of Californians

February 24, 2009

April Alameda, Program Analyst
Board of Chiropractic Examiners
2525 Natomas Park Drive
Suite 260
Sacramento, CA 95833

RE: Proposed Regulations Concerning Manipulation Under Anesthesia (MUA)

Dear Ms. Alameda,

The California Medical Association (CMA) appreciates the opportunity to comment on the proposed adoption of Title 16, California Code of Regulations §318.1. CMA is concerned that any regulation adopted by the Board of Chiropractic Examiners be consistent with statutory and decisional law, and in the best interest of patients. We do not believe that proposed regulation satisfies these obligations. To the contrary, the proposed regulation is inconsistent with statutory and initiative measures designed to protect the public health by strictly regulating the scope of practice of chiropractors and the performance of procedures in health care facilities in California. As such, the proposed regulation fails to meet the authority and consistency standards at California Government Code §11349.1 and must be rejected. Further, the CMA questions the necessity of the proposed regulation in authorizing a treatment for which the efficacy, safety, and clinical indication remain unfounded by reliable scientific study.

I. THE PROPOSED REGULATION VIOLATES SECTION 7 OF THE CHIROPRACTIC ACT

Any regulation purporting to authorize chiropractors to manipulate patients while they are under anesthesia is invalid as beyond the scope of practice of chiropractic. Section 7 of the Chiropractic Act, which carefully limits the scope of a chiropractor's license, provides:

> One form of certificate shall be issued by the Board of Chiropractic Examiners, which said certificate shall be designated "licensed to practice chiropractic", which license shall authorize the holder thereof to practice chiropractic in the State of California as taught in chiropractic schools or colleges; and, also, to use all necessary mechanical, hygienic and sanitary measures incident to the care of the body, but shall not authorize the practice of medicine, surgery, osteopathy, dentistry or optometry, nor the use of any drug or medicine now or hereafter included in materia medica.

This provision was adopted as an initiative measure in 1922 by the people of the State of California. Accordingly, the scope of chiropractic practice can only be expanded by a vote of the majority of the people in this state. *See* California Constitution, Article II, Section 10(c),

Article IV, Section 1. Since the adoption of this narrowly drawn initiative measure, the wording of Section 7 has never been modified.

Through the years, there have been a number of court opinions construing Section 7 of the Chiropractic Act. The courts have consistently and repeatedly held that the practice of chiropractic must not extend beyond its scope as that term was originally understood, defined, and taught when the Chiropractic Act was initially enacted. *See* generally *In re Hartman* (1936) 10 Cal.App.2d 213, *People v. Fowler* (1938) 32 Cal.App.2d Supp. 737, *Crees v. Board of Medical Examiners* (1963) 213 Cal.App.2d 195, *Tain v. Board of Chiropractic Examiners* (2005) 130 Cal.App.4th 609. As a result, to fall within the chiropractic scope of practice, the activity:

(1) Must be understood as chiropractic in its ordinary and general sense as the term was understood in 1922;

(2) Must have been taught in chiropractic schools in 1922;

(3) Must not involve any incidental mechanical and hygienic measures that invade the field of medicine and surgery;

(4) Does not involve the practice of medicine;

(5) Does not involve the use of drug or medicine now or hereafter included in materia medica.

Any proposed regulation allowing chiropractors to perform manipulation under anesthesia violates each and everyone one these prongs.

A. Chiropractic MUA Is Not a Chiropractic Method

Performing manipulation under anesthesia does not fall within the term of "chiropractic" as that term was understood in 1922. This issue was fully analyzed in *People v. Fowler*, *supra*. There, the court referred to several commonly used dictionaries available at the time the Chiropractic Act was enacted, including the "Standard Dictionary, 1913 Edition" which defined chiropractic as:

> a **drugless** method of treating disease chiefly by manipulation of the spinal column.

(*Id.* at 745, emphasis added.) The court then went on to cite numerous other opinions and references defining chiropractic essentially the same way.

The concept of being "drugless" was key to the concept of chiropractic in 1922 as well as to the Initiative Act's passage. As recited by *People v. Fowler*, the Act was "intended to continue as to chiropractors the limitations imposed on drugless practitioners by the Medical Practice Act, that

is, to deny them the use of drugs and medical preparations and the severing or penetrating of the tissues of human beings." (*Id.* at 750.)

"Drugless practice," in fact, was the understanding of the people when voting for the Chiropractic Initiative Act in 1922. An examination of the argument in favor of the Chiropractic Act, as it was presented to the voters in 1922, makes it plain that the voters understood that chiropractors were to be "drugless practitioners," performing a different system of curing than physicians. In fact, the argument in favor of the proposed Chiropractic Acts notes that licensees under the proposed board would receive more training (presumably than physicians) in the "drugless section of the [then] present Medical Act" and that the "teachings and practice of chiropractic are admittedly different from those of medicine." These statements, while not conclusive, are an important interpretation in the Act. (*People v. Fowler*, *supra* at 745.) Under these circumstances, the concept of injecting medications into a practice of chiropractic is wholly inconsistent with what the voters intended and what is expressly stated in Section 7 of the Chiropractic Act.

B. Chiropractic MUA Was Not Taught in Chiropractic Schools in 1922

For something to fall within Section 7, it must not only have been understood to be chiropractic in 1922, it must also have been taught in chiropractic schools or colleges at the time. While the trial court in *Crees* did suggest that chiropractic is not a "static system of healing," appellate courts in both *Crees* and a more recent case interpreting the scope of practice of chiropractic, *Tain*, expressly and unequivocally limited the practice of chiropractic to that was taught in 1922 as any other result would allow chiropractic school administrators to control the scope of practice of chiropractic. *See*, *Tain*, *supra* at 620.

There is little question that MUA was not taught in chiropractic schools in 1922. In fact, a recent article set forth in the "Spine Journal" described the history of the activity in question as follows:

> Various forms of MAM (medicine assisted manipulation) have been used since the 1930s and several studies were published on MUA in the 1940s and 1950s when it was practiced by orthopedic surgeons and osteopathic physicians. Early methods for MUA were very different from the modern practice of MAM. Complications from general anesthesia and forceful, long-lever, high-amplitude nonspecific manipulation procedures led to decreased use of early MUA procedures in favor of surgery or other pain management therapies. Once it had been largely abandoned by orthopedic surgeons in the 1960s, MUA was modified and revived in the 1990s by chiropractors, and, to a lesser extent, osteopathic physicians. The resurgence of MAM was likely the result of increased interest in spinal manipulative therapy (SMT) and the advent of safer, shorter-acting anesthesia agents used for conscious sedation.

See Simon Dagenais, DC, Ph.D., et al., "Evidence-informed management of chronic low back pain with medicine-assisted manipulation," The Spine Journal 8 (2008) 142-149.

Short of any direct evidence through curricula that chiropractic schools were in fact teaching this procedure in 1922, the proposed regulation must be rejected for failing to meet this prong for determining the lawful scope of chiropractic practice.

C. Chiropractic MUA Invades the Field of Medicine and Surgery

Nor is the practice of MUA a permissible necessary "mechanical, hygienic and sanitary measure" incident to chiropractic since the use of anesthesia invades the field of medicine. *See, People v. Nunn* (1944) 65 Cal.App.2d 188, 194 (stating, "he is limited to the use of mechanical hygienic measures incident to the care of the body which do not invade the field of medicine and surgery.") Clearly, since drugs and anesthesia involves the field of medicine, the use of it cannot constitute a mechanical, sanitary or hygienic measure.

D Chiropractic MUA Constitutes the "Use of Any Drug or Medicine" for the Purposes of Section 7

Another reason the regulation as proposed is invalid is that Section 7 itself expressly prohibits "the use of any drug or medicine now or hereinafter included in materia medica." Significantly, Section 7's language expressly prohibits the broad term "use" as opposed to the narrower term "prescribe." Such terms, should of course, be construed in accordance with their usual and ordinary meaning. *See People v. Snook* (1997) 16 Cal.4th 1210, 1215. Black's Law Dictionary (8th Ed. 2004) defines the term "use" as "the application or employment of something." Thus, the fact that the chiropractor his or herself does not actually apply or administer the anesthesia does not mean that the activity is lawful for the purposes of Section 7. Employing, that is, using someone to do something that chiropractics themselves may not, is illegal.

II. THE PROPOSED REGULATION IS INCONSISTENT WITH LAWS GOVERNING CALIFORNIA HEALTH FACILITIES

In addition to the profound expansion of scope of practice chiropractic practice, proposed subdivision (a) contains a number of problems that are inconsistent with current California law. For example, hospitals simply are not accredited by a number of organizations listed in the regulations. Second, ambulatory surgical centers may be accredited, but only by those that are deemed to be an accrediting organization approved by the Medical Board of California. *See* Health & Safety Code §1248.1. The Medical Board's website currently does not identify the Det Norske Veritas Healthcare Inc. as an accrediting organization.

Subdivision (b) similarly is unclear. For example, who is an "other healthcare provider authorized under California law to administer anesthesia." Nurse anesthetists are authorized to administer anesthesia, but they may only do so under the supervision of a physician. The regulation is silent as to who may perform such anesthesia and under what circumstances. Short

of further definition, we believe that the regulation fails to meet the "clarity" requirement of the Administrative Procedure Act.

III. THE NECESSITY OF THE PROPOSED REGULATION HAS NOT BEEN ADEQUATELY ESTBLISHED

Government Code §11349 (a) defines the burden of necessity as the demonstration of "substantial evidence that the need for regulation to effectuate the purpose of the statute, court decision or other provision of law that the regulation implements." One of the guiding tenants of the Chiropractic Act of 1922 is the protection of the public and in fact this is cited as rationale for the necessity of MUA regulation. The procedure itself is proposed as a treatment for chronic lower back pain as well as a range of other dysfunctions including motion restriction after trauma and muscle contraction. These indications however, remain experimental given the lack of data confirming the efficacy and long term effects of MUA. A review of clinical studies on MUA published in The Spine Journal in 2008, found that the available case studies on the treatment "had poor methodological quality, lacked control groups, and an incomplete understanding of purported benefits of combining spinal manipulative therapy with anesthesia." The article concludes by noting the following:

> There is a strong need for comparative clinical trials, large cohort studies, and experimental studies to support the theories on which these treatment approaches are based...There is insufficient research to guide clinicians, policy makers, and especially patients' decision whether to consider this treatment approach.

See Simon Dagenais, DC, Ph.D., et al., "Evidence-informed management of chronic low back pain with medicine-assisted manipulation," The Spine Journal 8 (2008) 142-149.

Another review of data concluded that information on the effectiveness of MUA protocols are largely anecdotal and require additional study. *See Medication-assisted Spinal Manipulation, Kohlbeck, et al 2002.* Even more telling, The Guidelines for Chiropractic Quality Assurance and Practice Parameters published as the result of a consensus conference of chiropractic practitioners, gave MUA a rating of "equivocal", noting that its value can neither be confirmed nor denied. *See Guidelines for Chiropractic Quality Assurance and Practice Parameters: Proceedings of the Mercy Center Consensus Conference, S Haldeman et al (eds.), Edition: 2, 2004.*

In recognition of this lack of evidence supporting the clinical indications for MUA, a number of third party payers have determined not to cover spinal manipulation under anesthesia. Aetna considers the procedure "experimental and investigational". *See Aetna, Clinical Policy Bulletin: Manipulation Under Anesthesia Number: 0204.* Anthem Blue Cross of California makes similar findings related to MUA on the basis that there lacks controlled studies to isolate and measure the actual effectiveness of the treatment. *See Anthem, Medical Policy #MED.00079.* The United Healthcare policy on the procedure notes the following:

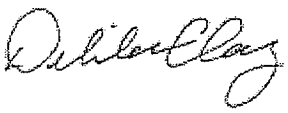
> MUA has been reported by various sources as clinically indicated for a broad range of conditions. Many of these conditions represent vague or diagnostically elusive entities. Most of these conditions lack any research evidence on the predictive value of MUA, appropriate dose and safety.

See United Healthcare, Spinal Manipulation Under Anesthesia, Policy #: ANESTHESIA 003.3 T2

The absence of reliable study on the indications for and results of MUA call into serious doubt, the necessity of this regulation. It would seem that a critical step in the protection of the public has been forgone given the experimental nature of this treatment.

In conclusion, CMA appreciates the opportunity to comment on this regulation but believes it is fraught with problems. Accordingly, CMA urges that it be withdrawn.

Sincerely,



Delilah Clay
Research Associate, Medical and Regulatory Policy
California Medical Association

CALIFORNIA CHIROPRACTIC ASSOCIATION

February 24, 2009

Fred Learner, DC, Chair
Board of Chiropractic Examiners
2525 Natomas Park Drive, Suite 260
Sacramento, California 95833

RE: Proposed MUA Regulations

Dear Dr. Lerner:

The California Chiropractic Association (CCA) is pleased to support the state Board of Chiropractic Examiners (BCE) proposed regulations establishing standards of care for manipulation under anesthesia (MUA). MUA is the manipulation of a patient who is sedated by the administration of anesthesia by a physician and surgeon or other health care provider who is legally authorized to administer anesthesia.

The regulation is necessary to clarify that the provision within the chiropractic scope of practice prohibiting the use of drugs pertains only to the activities by a doctor of chiropractic and does not preclude a doctor of chiropractic from participating in a procedure where a qualified anesthesia provider is entirely responsible for the administration and monitoring of the drugs. The proposed regulation in no way increases the scope of practice of chiropractic. It simply ensures patient safety by establishing minimum safety requirements for a procedure that has been practiced safely by doctors of chiropractic in California for more than 20 years.

The regulation protects the public by ensuring there is no threat of a doctor of chiropractic invading the field of medicine. The regulation clearly states that the "chiropractor may not direct, instruct, interfere, or make any orders to the physician and surgeon, or other health care provider who is administering and maintaining the anesthesia." The regulation also strictly prohibits chiropractors from being involved in or interfering with the physician and surgeon or other health care provider in the discharge of the patient. During the MUA procedure, the chiropractor is simply practicing alongside the anesthesia provider in performing manipulation procedures that are clearly within the doctor of chiropractic's scope of practice. A chiropractic practitioner can work – and often does - in tandem with a medical doctor without medical treatment performed by the medical doctor being attributed to the doctor of chiropractic.

The regulation further protects the public because it requires the procedure to be performed in a hospital or ambulatory surgery center that is properly licensed and regulated. The strict, well-defined standards and regulations that help keep anesthesia very safe in hospitals and surgical centers do not uniformly apply to medical doctor offices. Without this BCE-proposed regulation, MUA may be taking place in environments with limited or outdated equipment, few or no emergency resources, inadequately trained staff or insufficient safety precautions.

Thank you for proposing this important regulation that will protect the health and safety of the public.

Sincerely,

David Benevento DC

David Benevento, DC
President

Dear Members of the California Chiropractic Board,

I urge you to pass the new proposed legislation on the regulation of manipulation under anesthesia (MUA). I think some type of regulation in regard to MUA is long overdue. The jailing of 4 chiropractors in California for clearly practicing within the scope of chiropractic was tragic, and harmful to their patients, the public which you as board members are mandated to protect. There are several reasons I think regulation is necessary:

1) MUA is highly effective in the most difficult spine, and extremity cases. Depending on the research sited, the effectiveness is 70-90%, in cases in which many other treatments have failed or have had limited success with a plateau, including surgery, traditional chiropractic, pain management procedures (radiofrequency oblation), epidurals, trigger point injections, etc.[1] This is truly a procedure that gives back tremendous return of quality of life to patients.

2) Chiropractors or co-management with a chiropractor and a physician is the most appropriate way for MUA to be administered due to the safety record of chiropractic in MUA. MUA traditionally performed by doctors of osteopathy carried greater risks of serious complications due to long lever adjusting.[2,3]

3) The proposed legislation is very clear and is consistent with the recent court decision exonerating the previously jailed doctors of chiropractic. It does not duplicate or conflict with any existing legislation regarding chiropractic.

4) The proposed legislation addresses standard of care quite nicely and failure to meet standard of care.

5) The safety and effectiveness of this procedure when performed by chiropractors or multidisciplinary with a chiropractor involved make this a procedure that is highly beneficial for patients, and necessitate the board protecting the rights of the public to receive this procedure performed by chiropractors or a multidisciplinary chiropractic team when appropriate.

Sincerely,

Annette K. Cassity, D.C.

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[1] Spine J 8, 2008 Dagenais, DC, PhD, John Mayer DC, PhD, James Wooley, DC, Scott Haldeman, DC, MD, PhD, Evidence-informed management of chronic low back pain with medicine assisted manipulation. page 142-149

[2] Spine J 8, 2008 Dagenais, DC, PhD, John Mayer DC, PhD, James Wooley, DC, Scott Haldeman, DC, MD, PhD, Evidence-informed management of chronic low back pain with medicine assisted manipulation. page 142-149

[3] Kohlbeck FJ, Haldeman S., Medication assisted spinal manipulation Spine J 2002; 2: 288-302

Attachment C

Modified Proposed Regulatory Language for MUA

Section 318.1 is hereby added to Title 16, Division 4, Article 2 of the California Code of Regulations:

318.1 **Standard of Care re Manipulation Under Anesthesia (MUA)**

(a) MUA may only be performed in a hospital or ambulatory surgery center that is licensed by the California Department of Public Health, Bureau of Hospital Licensing and Certification or ~~a hospital or~~ *in an* ambulatory surgery center *operating pursuant to Section 1248.1 of the Health and Safety Code or* that is accredited by ~~the Joint Commission on Accreditation of Healthcare Organizations, the American Association for Accreditation of Ambulatory Surgery, the Accreditation Association for Ambulatory Health Care, Medicare, Det Norske Veritas Healthcare Incorporated, or the Institute for Medical Quality. If any of the above named organizations changes its name the Board shall continue to recognize the organization.~~ *an agency approved by the Medical Board of California pursuant to Chapter 1.3 of Division 2 of the Health and safety Code (commencing with Section 1248).*

(b) Anesthesia may only be administered, *following an appropriate prior examination,* by a California licensed physician and surgeon *trained and competent to administer anesthesia safely*, or other health care provider authorized under California law to administer anesthesia. The chiropractor may not direct, instruct, interfere, or make any orders to the physician and surgeon, or other health care provider who is administering and maintaining the anesthesia.

(c) MUA shall be performed by two chiropractors trained and competent to safely perform MUA. The "primary chiropractor" shall formulate the chiropractic portion of the MUA treatment plan and shall be responsible for performing the chiropractic manipulation for that procedure. The "second chiropractor" shall insure that all movements are accomplished with patient care and safety as his or her primary focus and shall assist the "primary chiropractor" when necessary. The chiropractic portion of MUA is limited to techniques within the scope of practice of a chiropractor.

(d) For the purpose of this section, the primary chiropractor and the second chiropractor may not be involved in nor interfere with the physician and surgeon or other health care provider in the discharge of the patient following the MUA procedure.

(e) Failure to follow the standard of care contained in this section when performing MUA shall constitute unprofessional conduct.

(f) MUA means the manipulation of a patient who is sedated by the administration of anesthesia by a physician and surgeon or other health care provider who is legally authorized to administer anesthesia.

Board of Chiropractic Examiners
Proposed Regulatory Language for Continuing Education
California Code of Regulations, Title 16, Division 4, Article 6

§355. ~~Renewal and Restoration.~~ Annual License Renewals

(a) ~~Commencing with the renewal period for 1973, each licensee and each applicant for restoration of a license forfeited for failure to renew shall, as a condition to renewal or restoration of his license and in addition to paying the annual renewal fee of one hundred fifty dollars ($150.00) or restoration fee of double the annual renewal fee as provided by section 12 of the Act (California Business and Professions Code section 1000-12), submit proof that he has completed within the past 12 months a course of continuing education approved by the board on a form (No. 09RA-1 (8/91) provided by the board titled Renewal Application. The Renewal Application as provided by the board will indicate the current year of renewal.~~ To renew a license, a licensee shall complete and submit a "Renewal Application," (Revision date 1/09) form which is incorporated by reference, and pay the annual renewal fee of one hundred fifty dollars ($150). The renewal application and renewal fee shall be submitted to the board prior to the expiration date of the license. The board will not process incomplete applications or complete applications that do not include the correct renewal fee.

In addition to any other requirement for renewal of a license, a licensee shall disclose whether, since the last renewal of his or her license, he or she has been convicted of any violation of the law in this or any other state, the United States, or other country. However, licensees are not required to disclose traffic infractions that resulted in fines of less than five hundred dollars ($500) that did not involve alcohol, dangerous drugs, or controlled substances.

(b) ~~In lieu of submitting the proof of completion of continuing education required under subsection (a) above, any such licensee or applicant may submit a statement, which shall be verified or certified under penalty of perjury, that he or she will not engage in the practice of Chiropractic within the State of California during the period for which renewal or restoration is sought unless he or she first completes an approved course of continuing education and submits proof thereof to the board; and that he or she understands that failure to do so will constitute grounds for the suspension or revocation of his or her license. A license that has expired for~~

~~failure to renew may be renewed at any time within three years after the expiration date. If no application is received within three years, the Board shall cancel the license.~~ To restore a license in forfeiture status to active status, an applicant shall complete and submit a "Restoration Forfeiture Application," form (Revision date 1/09) which is hereby incorporated by reference, and pay the license restoration fee.

The restoration application must be submitted to the board within the period that the license is in forfeiture status. A license that has not been renewed after five (5) years has elapsed from the license expiration date is deemed cancelled and is not eligible to be restored under this section.

In addition to the application requirement, an applicant shall have met one of the following:

(1) Completed the board's continuing education requirements that were in effect at the time for each year the license was expired;

(2) Practiced in another state under an active valid license and completed all continuing education requirements for that state for each twelve (12) month period or portion thereof the license was expired;

(3) Passed the National Board of Chiropractic Examiners (NBCE) Special Purposes Examination for Chiropractic examination within six (6) months prior to submitting the license restoration application.

(c) ~~To restore a cancelled license, the person must submit to the Board's office, in compliance with the application instructions, an application for restoration, pay a fee of twice the annual amount of the renewal fee, and provide evidence of Board-approved continuing education, as specified in California Code of Regulations, section 356, for each 12-month period in which the license was cancelled. Continuing education required to restore a cancelled licensed must be commenced and completed during the 12-month period immediately preceding the request for restoration.~~

The renewal fee for a license in an inactive status shall be the same fee assessed for renewal of an active license. Licensees holding an inactive license shall be exempt from continuing education requirements. The holder of an inactive license may not engage in the practice of chiropractic during the time that his or her license is inactive. To return an inactive license to active status, the licensee shall complete and submit the "Inactive to Active Status," form (Revision date 1/09), which is hereby incorporated by reference, and pay a fee of thirty-five dollars ($35).

In addition to the application requirement, an applicant shall have met one of the following:

(1) Completed the board's continuing education requirements that were in effect at the time for each year the license was expired;

(2) Practiced in another state under an active valid license and completed all continuing education requirements for that state for each twelve (12) month period or portion thereof the license was expired;

(3) Passed the National Board of Chiropractic Examiners (NBCE) Special Purposes Examination for Chiropractic examination within six (6) months prior to submitting the license restoration application.

(d) ~~Licenses for doctors of chiropractic which heretofore expired on the last day of December each year will henceforth expire on the last day of the birth month of the licensee in each year.~~

~~To facilitate the conversion to the birthdate renewal system for doctors of chiropractic, licenses that expire on December 31, 1991 will be renewed for periods from seven (7) to eighteen (18) months. The fee to be paid shall be that determined by multiplying 1/12 of the renewal fee by the number of months of licensure in accord with the following schedule. All fees shall be rounded to the nearest whole dollar.~~

~~Licensees Born In~~	~~Will Be Licensed for The Period~~	~~Months of Licensure~~
~~January~~	~~January 92-January 93~~	~~13~~
~~February~~	~~January 92-February 93~~	~~14~~
~~March~~	~~January 92-March 93~~	~~15~~
~~April~~	~~January 92-April 93~~	~~16~~
~~May~~	~~January 92-May 93~~	~~17~~
~~June~~	~~January 92-June 93~~	~~18~~
~~July~~	~~January 92-July 92~~	~~7~~
~~August~~	~~January 92-August 92~~	~~8~~
~~September~~	~~January 92-September 92~~	~~9~~
~~October~~	~~January 92-October 92~~	~~10~~
~~November~~	~~January 92-November 92~~	~~11~~
~~December~~	~~January 92-December 92~~	~~12~~

~~This will be a one time reduction or increase, effective January 1992 all licenses will be annually renewed on a birthdate renewal system.~~

~~This subsection shall remain in effect until June 30, 1993, and on such date is repealed.~~ The board shall cancel a license if it not renewed within five (5) years of the license expiration date. Applicants may apply to restore a cancelled license after two (2) years have elapsed from the license cancellation date as specified in section 10 (c) of the Act.

To restore a cancelled license, an applicant shall complete and submit an "Application for Restoration after Cancellation," form (Revision date 1/09), which is hereby incorporated by reference, and pay a fee of twice the annual renewal fee.

In addition to the application requirement, an applicant shall have met one of the following:

(1) Provided evidence that he or she has completed the board's continuing education requirements that were in effect for each year the license was expired;

(2) Practiced in another state under an active valid license and completed all continuing education requirements for said state for each twelve (12) month period or portion thereof the license was expired;

(3) Passed the National Board of Chiropractic Examiners (NBCE) Special Purposes Examination for Chiropractic examination within six (6) months prior to submitting the license restoration application.

§355.1. Continued Jurisdiction of a License.

The suspension, expiration, cancellation or forfeiture by operation of law of a license issued by the board, or its suspension, or forfeiture, by order of the board or by order of a court of law, or its surrender without the written consent of the board shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.

~~**§355.2. Inactive License.**~~

~~A licensed chiropractor may apply to the board to request that his or her license be placed on inactive status. An inactive license shall be renewed during the same time period at which an active license is~~

~~renewed. The renewal fee for a license in an inactive status shall be the same fee assessed for renewal of an active license. Licensees holding an inactive license shall be exempt from continuing education requirements.~~

~~The holder of an inactive license shall not engage in the practice of chiropractic during the time the license is inactive.~~

~~Licensees on inactive status who have not committed any acts or crimes constituting grounds for discipline may submit a written request for an active license and the following:~~

~~(a) Evidence of board-approved continuing education for each 12-month period or portion thereof the license was inactive. The continuing education must be taken prior to the request for activation and shall comply with California Code of Regulations section 356; or~~

~~(b) If practicing in another state, provide proof of licensure and continuing education from that state for each 12-month period the license was inactive in California.~~

§356. ~~Course Content.~~ Continuing Education Requirements

~~All doctors engaged in active practice, whether on a full-time or part-time basis, shall complete a minimum of twelve (12) hours per licensing year of continuing education courses approved by the board.~~

~~The board shall consider for approval the application of any continuing education course which conforms to the criteria below and is sponsored by a board approved continuing education provider.~~

~~A continuing education course may contain more than twelve (12) hours of approved subject material. Any twelve (12) approved hours may be selected for continuing education credit, provided, however, the same course may not be attended more than once for credit within that licensing year, and four (4) hours of every twelve (12) hours selected for continuing education credit must be in the subject area of adjustive technique. The four (4) hours in adjustive technique may be satisfied by lecture and demonstration.~~

~~The basic objectives and goals of continuing education are the growth, maintenance of knowledge and competency, the cultivation of skills, and greater understanding, with a continual striving for excellence in chiropractic care and the improvement in the health and welfare of the public.~~

~~(b) Each course approved by the board must present subject material directly related to the concepts of chiropractic principles and practice including diagnostic procedures, patient care and management. The board recommends special attention be given to the following:~~

~~(1) Principles of practice of chiropractic and office procedures including, but not limited to:~~

~~(A) Chiropractic treatment and adjustment technique, including physiotherapy, nutrition and dietetics;~~

~~(B) Examination and diagnosis or analysis including physical, laboratory, orthopedic, neurological and differential;~~

~~(2) Radiographic technique and interpretation involving all phases of roentgenology as permitted by law;~~

~~(A) Study of the methods employed in the prevention of excessive radiation and safety precautions to the patient;~~

~~(3) Postgraduate studies including, but not limited to, subjects contained within groups one through six of Section 5 of the Chiropractic Initiative Act;~~

~~(4) Insurance procedures and reporting~~ Licensees shall complete a minimum of twelve (12) hours of board approved continuing education courses during the year preceding his or her annual license renewal period. However, effective January 1, 2010 the number of required hours shall be increased to twenty-four (24) hours of board approved continuing education courses during the year preceding his or her annual license renewal period. A maximum of six (6) hours of continuing education may be completed through distance learning pursuant to the requirements set forth in section of these regulations. However, effective January 1, 2010 maximum of twelve (12) hours of continuing education hours may be completed through distance learning as described above. Any continuing education hours accumulated before January 1, 2010 that met the requirements in effect on the date the hours were accumulated will be accepted by the board for license renewals taking place on or after January 1, 2010. It is the responsibility of the licensee to actively participate in the continuing education course by remaining focused on the material being presented throughout the duration of the course. Licensees shall complete continuing education courses as prescribed below:

(a) MANDATORY:

Each licensee shall complete a minimum of four (4) hours of instruction in any one of, or a combination of, the following courses:

1) The vertebral subluxation complex and somato-visceral, viscero-somatic reflexes including their relationships between disease and health.

2) Instruction in various, basic to comprehensive physical examination procedures, which at a minimum shall

include orthopedic, neurological and general diagnosis related to evaluation of the neuro-musculoskeletal systems, but may also address differential diagnose of various conditions that affect the human body, provided this instruction is consistent with the provisions of section 302. 3) The interpretation of various diagnostic imaging procedures and technologies, clinical chemistry analysis and interpretations, to assist the doctor in differential diagnosis of disorders or diseases which help to better analyze and treat patients, as long as these are consistent with the provisions set forth in section 302.

(b) CATEGORY I:

Each licensee shall complete a minimum of ten (10) hours in any of the following courses or subject matter:

(1) Chiropractic adjustive technique or chiropractic manipulation techniques.

(2) Taking and recording an accurate and detailed patient history.

(3) Procedures and techniques related to differential diagnosis; including diagnostic testing: clinical chemistry and related laboratory analysis; diagnostic x-ray; MRI; PET Scan; Bone Scan; CT Scan; and any other advanced imaging studies or procedures;

(4) Pain management including current trends in treatment and instruction in the physiology and anatomy of acute, sub-acute and chronic pain;

(5) Physiotherapy techniques, including the theory of and application of physiotherapies, including but not limited to: ultrasound including extracorporeal shock wave therapy; therapeutic laser, electric stimulation modalities; heat and cold, short wave diathermy;

myofascial release; massage therapies; and instruction in the physiology of and appropriate use for physiotherapy.

(6) Instruction in manipulation under anesthesia including the safe handling of patients under anesthesia.

(7) Instruction in various aspects of geriatric and pediatric care as related to the practice of chiropractic.

(c) CATEGORY II:

Each licensee shall complete a minimum of ten (10) hours in any of the following courses or subject matters or attendance of board meetings:

(1) Courses that are approved by the California Department of Industrial Relations, Division of Workers Compensation;

(2) Courses that are approved by any Healing Arts or Bureau within Division 2 of the Business and Professions Code or approved by any organization authorized to approve continuing education by any Healing Arts or Bureau in Division 2 of the Business and Professions Code;

(3) Instruction in proper and ethical billing and coding, including accurate and effective record keeping and documentation of treatment, evaluation and progress of their patient;

(4) Truth in advertising;

(5) Ethics and law: including professional boundaries, mandatory reporting requirements for child abuse/neglect, elder abuse/neglect, spousal abuse/neglect; review of the specific laws, rules and regulations related to the practice of chiropractic in the State of California;

(6) Adverse event avoidance, including reduction of potential malpractice issues;

(7) Pharmacology, including side effects, drug interactions of various commonly prescribed and over-the-counter drugs, blood and urinalysis testing used in the diagnosis and detection of disease, including use of and interpretation of urinalysis and drug testing strips or kits.

(8) Philosophy of chiropractic, including the historical development of chiropractic as an art and science and health care approach.

(9) Cardiopulmonary resuscitation: A licensee may earn a maximum of two (2) hours.

(10) Board Meeting: A licensee shall earn a maximum of four (4) hours of continuing education credit in Category II for attending a full meeting that includes the hearing of cases related to petitioners seeking the reinstatement of revoked licenses or early termination of probationary licenses. A petitioner may not earn any continuing education credit for attending a board meeting on the same day in which said petitioner's hearing is conducted. A licensee may earn a maximum of four (4) hours of continuing education credit for the license renewal period under this subsection.

~~**§356.1. Cardiopulmonary Resuscitation/Basic Life Support Training.**~~

§356.5. Continuing Education Provider Approval, Duties, and Responsibilities.

(a) ~~In order to become and remain eligible for approval by the board as a continuing education provider, each provider must comply with provisions (b)(1) through (b)(10) of this section and provisions of section 357. Failure to comply with these provisions may result in the withdrawal of approval of the provider by the board.~~

~~A provider that has had its approval withdrawn by the board shall not be eligible to provide continuing education credit until the board reinstates the provider.~~

~~A provider that has lost approval may reapply to the board for approval as a continuing education provider after a period of suspension established by the board at the time that approval is withdrawn not to exceed two years.~~ As used in this section, a provider is an individual, partnership, corporation, professional association, college or any other entity approved by the board to offer board approved continuing education courses to licensees to meet the annual continuing education requirement set forth in section 356 of these regulations.

(a) To apply to become a provider, an applicant shall complete and submit a "Continuing Education Provider Application" form (Rev. insert date) which is hereby incorporated by reference form, and pay a fee of thirty-five dollars ($35).

The board will not process incomplete applications or applications that do not include the correct application fee.

If an application is denied under this section, the applicant may request an informal hearing on the denial with the Executive Officer within 30 days of the denial date.

Upon request for informal hearing, the Executive Officer shall schedule the informal hearing within 30 days of receipt of request. Within 10 days following the hearing, the Executive Officer shall provide written notification of his or her decision to the applicant. If the Executive Officer upholds a denial under this section, the applicant may request a hearing on the denial before the board within 30 days of the denial date. Upon request for hearing, the Executive Officer shall schedule the hearing at a future board meeting but not later than 180 days. Within 10 days following the hearing, the Executive Officer shall provide written notification of the board's decision to the applicant. The board's decision shall be the final order in the matter. The approval of the provider shall expire two (2) years after it is issued by the board and may be renewed upon the filing of the required application and fee referenced in this subsection.

(b) ~~Each continuing education provider shall:~~

~~(1) Make written application to the board for approval as a continuing education provider, and also provide to the board a written mission statement that outlines the provider's continuing education objectives and declares the provider's commitment to conform to the standards set forth in this section. Applications for~~

~~approval shall be submitted to the board office at least 30 days prior to a scheduled board meeting. Providers with applications that are incomplete will be notified of the deficiencies in writing within three weeks from the date of receipt. Complete applications will be reviewed at the scheduled board meeting and notification of the board's decision will be provided in writing within two weeks following the board meeting;~~

~~(2) Have engaged in the business of providing education to licensed health care professionals consisting of no less than one course in each year of a five year period immediately preceding the date of application for approval by the board as a continuing education provider;~~

~~(3) Designate a person responsible for overseeing all continuing education activities of the provider and provide written notification to the board identifying that individual;~~

~~(4) Use teaching methods that ensure student comprehension of the subject matter and concepts being taught;~~

~~(5) Establish and maintain procedures for documenting completion of courses, retain attendance records for at least four (4) years from the date of course completion, and furnish the board with a roster of persons completing the course, including the name and state chiropractic license number of each course participant, within sixty (60) days of course completion. Failure to submit the list of course participants within sixty (60) days of course completion may be grounds for withdrawal or denial of course approval;~~

~~(6) Be responsible for maintaining full-time monitoring of course attendance. If any participant's absence from the room exceeds ten (10) minutes during any one hour period, credit for that hour shall be forfeited and such forfeiture shall be noted in the provider's attendance report submitted to the board as required in subsection (b)(5) of this section.~~

~~It shall further be the responsibility of the provider to see that each person in attendance is in place at the start of each course period. Failure to maintain proper attendance monitoring procedures may be grounds for withdrawal or denial of course approval;~~

~~(7) Ensure availability to course participants of meeting rooms, study aids, audiovisual aids, and self-instructional materials designed to foster learning and ensure student comprehension of the subject matter and concepts being taught;~~

~~(8) Disclose in any continuing education course advertising if expenses of the program are underwritten or subsidized by any vendors of goods, supplies, or services;~~

~~(9) Inform the board immediately of any event that may affect the provider's approval as a continuing education provider by the board;~~

~~(10) Inform the board in writing immediately of any change to the course that would affect the date, time or location when or where the course will be held.~~ Providers shall:

(1) Identify an individual responsible for overseeing all continuing education activities of the provider;

(2) Ensure that the instructors teaching Mandatory and Category I courses in section 356 of these regulations have taught for the previous five (5) consecutive years in the subject matter being taught;

(3) Establish and maintain procedures for documenting completion of courses, retain attendance records for four (4) years from the date of course completion and shall provide a course roster to the board upon written request. Course rosters shall include the names of all licensees, license numbers, and e-mail addresses if available. Failure to submit the roster upon written request by the within thirty (30) days may result in the withdrawal or denial of previous course approval and withdrawal of provider status;

(4) Maintain course instructor curriculum vitas or resumes for four (4) years, if applicable.

(5) Provide to each attendee a "Continued Education Course Survey" form (Dated 1/09) which is incorporated herein by reference at the conclusion of the course. A provider may not grant continuing education hours to a licensee who fails to complete and turn in a Continued Education Course Survey. Each provider shall retain all course surveys for four (4) years.

Upon written request of the board, providers shall provide all course surveys to the board within thirty (30) days of request.

(6) If a participant's absence from the room exceeds ten (10) minutes during any one hour instruction period, his or her credit for that hour shall be forfeited and such forfeiture shall be noted in the provider's attendance report in accordance with the section of these regulations.

(7) Ensure availability to course participants of meeting rooms, study aids, audiovisual aids, and self-instructional materials designed to foster learning and ensure student comprehension of the subject matter and concepts being taught;

(8) Disclose to prospective participants the names of the individuals or organizations, if any, who have underwritten or subsidized the course. Providers may not advertise, market, or display materials or items for sale inside the room where the actual instruction is taking place;

(9) Providers shall inform the board in writing immediately of any change to the date, time or location of the course.

(10) Providers shall provide a certificate of completion to licensees who completed the continuing education course. The certificate shall include the following information.

(a) Name of provider

(b) Course approval number

(c) Date(s) of course

(d) Licensee name

(e) License number

(f) Identify the course category, Mandatory, Category I, Category II and the number of hours the licensee earned in each category.

§357. Approval of Continuing Education Courses.

(a) ~~The application for approval of a continuing education course shall be submitted to the board office at least 45 days prior to the date of the course and shall include a nonrefundable application fee of $50.00 and any other documentary information required by the board pursuant to section 356.~~

~~The application fee for ongoing postgraduate courses presented by chiropractic institutions accredited by the Council on Chiropractic Education (C.C.E.) is due upon initial receipt of the application for approval, regardless of the number of course meetings in one calendar year.~~

~~Courses with schedules continuing into a second calendar year must submit a new application for the second year if continuing education credit hours are to be offered for that year. The new application for the second year must contain the required fee ($50.00).~~

~~If a course meets the criteria of the board, the board shall notify the provider when a course has been approved. Mention of such approval shall be included in announcements of the program and the printed~~

~~program itself as follows: "Approved by the California State Board of Chiropractic Examiners for license renewal."~~

~~(b) Any board member, or members, or board designee shall have the right to inspect or audit any approved chiropractic course in progress.~~

~~(c) The board, may, after notification and an opportunity to be heard, withdraw approval of any continuing education course, and shall immediately notify the provider of such action.~~ The basic objectives and goals of continuing education are the growth, maintenance of knowledge and competency, the cultivation of skills, and greater understanding, with a continual striving for excellence in chiropractic care and the improvement in the health and welfare of the public and this must be demonstrated in the programs presented.

(a) Providers must complete and submit a "Continuing Education Course Application" form (Revision date 1/09) which is hereby incorporated by reference, and pay the application fee of seventy five dollars ($75). Providers shall submit and complete one application for each continuing education course being offered. If an application is denied under this section, the applicant may request an informal hearing on the denial with the Executive Officer within 30 days of the denial date.

Upon request for informal hearing, the Executive Officer shall schedule the informal hearing within 30 days of receipt of request. Within 10 days following the hearing, the Executive Officer shall provide written notification of his or her decision to the applicant. If the Executive Officer upholds a denial under this section, the applicant may request a hearing on the denial before the board within 30 days of the denial date. Upon request for hearing, the Executive Officer shall schedule the hearing at a future board meeting but not later than 180 days. Within 10 days following the hearing, the Executive Officer shall provide written notification of the board's decision to the applicant. The board's decision shall be the final order in the matter.

(b) Only those courses that meet the following shall be approved:

(1) No more than eight (8) hours of instruction shall be given during a twenty four (24) hour period.

(2) Continuing education credit shall be based on at least fifty (50) minutes of participation in an organized learning experience. Class breaks shall be at the discretion of the instructor. However, the instructor shall not exceed three (3) hours of continuous instruction without a break of at least fifteen (15) minutes. Breaks shall not count towards a course hour. To assure attendance, the course provider or designated monitor shall

stamp or otherwise note, on each attendee's attendance form, that he or she was present during each hour of instruction.

(3) Continuing education courses offered through distance learning must be in a format approved by the board including manuals, compact disks, digital video or versatile discs, audio and video tapes, research projects, computer or Internet courses and other emerging formats.

Licensees are restricted from taking the same distance learning course within any license renewal period.

Distance learning courses shall:

(A) Disclose course curriculum vitaes or resumes.

(B) Explain the appropriate level of technology required for student to successfully participate in course.

(C) Make available technical assistance as appropriate to the format

(D) Contain security measures to protect learner's identity, course and related content.

(E) Establish deadline for completion.

(F) Allow for licensee and instructor interaction in a timely manner.

(G) Show formal outcome assessment of course.

(H) Instructional materials are reviewed annually to ensure they meet current professional standards.

(I) Require licensee to sign an affidavit of compliance and verify completion of enrolled hours of distance education.

(J) Distance learning courses are required to be marketed without promotional material or advertisements embedded in the continuing education course delivery system. The continuing education provider shall notify the licensee when he or she is leaving a continuing education site and directed to a promotional or sponsored site. Manufacturers of chiropractic products or services may not be endorsed or embedded into the course material.

(4) The board may not approve the following subjects for continuing education courses: financial management, income generation, practice management, collections, self-motivation, practice-building, and patient recruitment.

(5) Any material change of course content requires submittal of a new application.

(6) The board's designee, after notification, may withdrawal approval of any continuing education course, and

shall notify the provider of such action. The provider may appeal the decision to the Executive Officer within 30 days of such notice. The provider may appeal the Executive Officer's decision by requesting that the appeal be heard at a board meeting before the Board Members.

(7) The board or its designee shall not be restricted from inspecting, observing, or auditing any approved chiropractic course in progress, at no charge.

A provider may not issue a continuing education certificate of completion to a member of the board or it's designee who audited the continuing education course without paying a fee to attend the course.

§358. Exemptions and Reduction of Requirement

~~(a) All doctors of chiropractic specifically exempted from, or obtaining a reduction in continuing education requirements include the following:~~ The following licensees are exempt, entirely or in part, from the continuing education requirements of Section 356 of these regulations.

(1) Inactive licentiates;

(2) New licentiates in the year of initial licensure;

(3) ~~Teachers. A full-time teacher, as defined by C.C.E. regulation, shall be exempt from the required hours until no longer engaged in full-time chiropractic teaching.~~ Instructors who have taught for two consecutive years and currently teach clinical diagnosis, anatomy, physiology, or other core science courses for more than 20 hours per week at any Council on Chiropractic Education accredited college for at least six (6) months during any license renewal period year may earn twelve (12) hours of continuing education in either Category I or Category II courses.

(4) ~~Lecturers. A lecturer shall be given two hours credit for each hour of actual lecturing at a recognized course. Credit for the same course presentation shall be granted only once during each year.~~ Licensees who teach a board-approved continuing education course may earn one (1) hour of continuing education credit for each two (2) hours of lecture not to exceed twelve (12) hours during any license renewal period in either Category I or Category II courses. Credit for the same course presentation shall be granted only once during each year.

(5) ~~If a doctor is unable to attend a continuing education course due to ill health, credit may be granted by the board upon request for documented completion of twelve (12) hours of recorded or videotaped approved~~

~~continuing education course work. Such an exemption request must be made prior to the date that the required continuing education must be completed and in writing to the board's office and must also be accompanied by an attending doctor's statement. The licensee shall send to the board's office a signed affidavit affirming he or she has completed twelve (12) hours of approved continuing education tapes and must provide the board with the names and dates of the approved continuing education courses comprising the lecture tapes.~~ A licensee who is unable to attend continuing education courses due to a physical disability and provides written certification from a primary health care provider may be exempted from completing continuing education requirements.

(6) ~~Commissioners on Examination. Commissioners on Examination who administer the practical examination at least twelve (12) hours annually shall be exempt from the continuing education requirement in the years they act as Commissioners on Examination.~~ Licensees who participate both days as an examiner for the part four portion of the NBCE examinations shall receive a maximum of six (6) hours of continuing education credit for each two day examination period conducted by the NBCE during the license renewal period in either Category I or Category II courses. Examiners must provide written certification from the NBCE confirming the examiner's involvement in the exam.

(7) Active Board Members. Professional board members who have served one full year on the Board of Chiropractic Examiners shall be exempt from the continuing education requirement in each year of board member service.

(8) Licensees who author published articles related to the chiropractic profession may receive a maximum of twelve (12) hours of continuing education credit in either Category I or Category II courses for each research study published in a peer reviewed, nationally recognized, and scientifically based publication.A licensee may not earn more than a maximum of twelve (12) hours of continuing education hours under this subsection.

(9) Licensees on active duty of a branch of the armed forces of the United States may earn twenty four (24) hours of continuing education requirements through board-approved distant learning courses.

(10) Licensees who a attend a full board meeting that includes petitioner hearings for license reinstatements or probation modifications may earn a maximum of two (2) hours of continuing education in Category I. A

petitioner may not earn continuing education hours for attending his or her hearing. A licensee may not earn not earn more than two (2) hours of continuing education hours under this subsection.

§359. Revoked or Suspended Licenses.

Any person making application for reinstatement or restoration of a license which has been revoked or suspended may be required, as a part of the relief granted, to complete an approved course of continuing education, or to complete such study or training as the board may require.

§360. Continuing Education Audits.

The Board shall conduct random audits to verify compliance with Continuing Education requirements of active licensees. Licensees shall retain documents of completion issued to them at the time of attendance of Board-approved Continuing Education courses for a period of four (4) years from their last renewal and shall forward ~~such proof~~ these documents to the Board upon request. Licensees who fail to retain documents of completion shall obtain duplicate documents, from Board-approved Continuing Education providers, who shall issue duplicates only to licensees whose names appear on the providers' rosters of course attendees. The documents of completion shall be clearly marked "duplicate" and shall contain the licensees' names and license numbers, as well as providers' names, course approval numbers, dates of attendance, and hours earned. Licensees who furnish false or misleading information to the Board regarding their Continuing Education hours shall be subject to disciplinary action. Providers who present false or inaccurate verification of a licensee's participation shall lose their provider status for a minimum of ten (10) years.

PROPOSED REGULATIONS RE PETITIONERS

Petitions for Reinstatement.

(a) A petitioner pursuant to section 10 (c) of the Initiative Act whose license has been revoked or cancelled may not petition the board for reinstatement until two (2) years has elapsed since the effective date of the decision revoking the license or the date the license was cancelled.

(b) A petitioner pursuant to section 10 (c) of the Initiative Act who has had a petition for reinstatement denied may not file another petition until three (3) years has elapsed since the effective date of the most recent denial.

(c) A petitioner who is subject to section 1003 of the Business and Professions Code may not petition the board for reinstatement until ten (10) years has elapsed since the effective date of the decision revoking the license.

Board of Chiropractic Examiners
Proposed Regulations
Title 16, Division 4, California Code of Regulations

311.1 Chiropractic Specialties

The board recognizes those specialty programs that are recognized by the American Chiropractic Association, the International Chiropractors Association, and equivalent specialty programs as determined by the board.

NOTE: Authority cited: Sections 1000-4(b) and 1000-10, Business and Professions Code; and Chiropractic Initiative Act of California, Stats. 1923, p. 1xxxviii. Reference: Sections 1000-4(b) and 1000-10, Business and Professions Code; and Chiropractic Initiative Act of California, Stats. 1923, p. 1xxxviii.